IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

UNITED STATES OF AMERICA *ex rel.* PETER HUESEMAN,	)	
Plaintiff,	)	**5:14-cv-00212-XR**
v.	)	**Judge Xavier Rodriguez**
PROFESSIONAL COMPOUNDING CENTERS OF AMERICA, INC.,	)	
Defendant.	)	

DEFENDANT'S MOTION TO DISMISS
THE GOVERNMENT'S COMPLAINT IN PARTIAL INTERVENTION

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Defendant, Professional Compounding Centers of America, Inc. ("PCCA"), respectfully submits this Motion to Dismiss the Government's Complaint In Partial Intervention (Dkt. 66) ("government's Complaint" or "Complaint") under Federal Rules of Civil Procedure 12(b)(6), 8, and 9(b). PCCA respectfully requests oral argument on its Motion.

INTRODUCTION

After over six-years of investigation, the government's 50-page Complaint misstates or incorrectly pleads facts that undermine its central theory, and the very notion that PCCA engaged in fraudulent conduct. The crux of the government's Complaint is that PCCA knowingly reported "false" and fraudulently inflated Average Wholesale Prices ("AWPs") for active pharmaceutical ingredients it sold to compounding pharmacies resulting in TRICARE paying excess reimbursement to those pharmacies. However, the government's Complaint fails completely in putting PCCA or the Court on notice as to what PCCA's AWPs should have been during the relevant time period, or even what the proper measure of AWP should have been. For this, and other reasons articulated below, the government's Complaint fails to state a claim cognizable under the FCA as required by Federal Rule of Civil Procedure (the "rules" or "Rule") 12(b)(6), as its allegations are not plausible under Rule 8, nor appropriately particular under Rule 9(b).

First, the government's Complaint fails to adequately allege even the most rudimentary FCA requirement: a "**false** claim," which in this District must be "**objectively false**." The government's entire FCA case hinges upon its assertion that PCCA set "inflated" AWPs for active pharmaceutical ingredients it sold to compounding pharmacies who then submitted claims to the government's TRICARE program. Critically, and fatal to its Complaint, the government does not define AWP or point to any statutory or regulatory definition of AWP in existence at the time of the alleged activity. Instead, the government repeats conclusory assertions that PCCA's AWPs are "false," "fraudulent," and "inflated." At no point does the government allege what a "truthful"

AWP should be or how a company in PCCA's position should appropriately calculate AWP. The government cannot shirk its FCA obligation to sufficiently allege how, why, and by what measure PCCA's AWPs were objectively false.

Second, the Complaint also fails to clear the FCA's rigorous materiality threshold as laid out in *Universal Health Svs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176 (2016). As an initial matter, neither PCCA's products, nor the compounded medications incorporating them, were covered under TRICARE's regulations. The government fails to plead how PCCA's reported AWPs could be material to TRICARE's payment decision, when its decision to reimburse compounded medications containing PCCA's products violated its own codified regulations. Furthermore, notwithstanding its knowledge that AWP was an unreliable and undefined standard, TRICARE chose Express Scripts, Inc. (a company the government knew to have been accused of illegally profiting off of the fraudulent inflation of AWPs) to reimburse for non-covered compounded medications based on the AWP of the ingredients in those compounded medications. In other words, TRICARE was aware of the substance of the government's allegations in this case and continued to pay the claims anyway. Not only that, but they were aware of these facts when deciding how those claims should be reimbursed and who should reimburse them from the outset. This is not just classic *Escobar*, it is super-*Escobar* and requires dismissal.

Third, under the standard for reckless disregard laid out in *Safeco Ins. Co. of America v. Burr*, the government fails to allege either that PCCA's interpretations of TRICARE's complex and ambiguous reimbursement regime were objectively unreasonable, or that any authoritative guidance sufficient to warn PCCA that it's interpretation of those regulations was unreasonable existed. 551 U.S. 47 (2007). Regardless, the government does not meet the current knowledge standard in this district under *U.S. v. Caremark, Inc.*, because its allegations are based on a good

faith disagreement over those complex and ambiguous regulations. No. SA-99-CA-00914-WRF, 2008 WL 11280711, at *2 (W.D. Tex. Aug. 27, 2008). Given that PCCA still cannot divine the government's proposed alternate measure of AWP, it is hard to understand how PCCA could have had knowledge of the government's preferred manner of calculating AWP at the time of the alleged conduct.

Fourth, the government's causes of action tied to alleged violations of the Anti-Kickback Statute ("AKS") should be dismissed, because the government fails to allege any item or service for which reimbursement "may be made" by TRICARE. PCCA's products and compounded medications incorporating them were not covered by TRICARE. Moreover, the government alleges, without adequately describing, two types of remuneration – the spread between PCCA's product costs and its reported AWPs and vacations allegedly offered to some unidentified customers by PCCA. However, the government fails to plead any particularized amount (or formula for calculating a particularized amount) of PCCA's reported AWPs that were fraudulent, and thus fails to meet Rule 9(b)'s heightened pleading standard as to the remuneration alleged. Similarly, the government fails to allege facts sufficient to tie the alleged vacations offered to some PCCA customers to any claim with which it now takes issue, thus falling short of Rule 9(b)'s pleading standard.

Fifth, the government's bootstrapped common law claims suffer from the same deficiencies as the government's FCA claims; as a result, they also fail. Moreover, the government fails to allege facts necessary to independently meet the elements of those claims.

Finally, the Complaint also fails to adequately plead causation. The Complaint's numerous analytical gaps, legal deficiencies, and improper conclusory assertions are nothing more than a smoke screen designed to distract this Court from TRICARE's and its contractor's own conduct

that directly caused any loss the government alleges exists. TRICARE designed its own unregulated reimbursement marketplace for compounded medications and elected to use AWP as the basis for reimbursement, while not defining it. TRICARE's own conduct and the conduct of third parties resulting from TRICARE's decision to violate its own regulations preempt and belie any causal connection between PCCA's alleged conduct in this case and the loss the government alleges.

For these reasons, and those articulated in more detail below, the Court should dismiss the entire Complaint.

FACTUAL BACKGROUND

I. PCCA and the Compounding Pharmacy Industry.

Compounding "serve(s) an important medical need for certain patients" that readily available prescriptions cannot cure. *See* Dkt. 66, ¶ 1, n.1. As a supplier of active pharmaceutical ingredients and bases used to make physician prescribed compounded drugs, PCCA is one link in a long compounding supply chain process. *Id.*, ¶ 1. The government's Complaint alleges that PCCA purchases active pharmaceutical ingredients from manufacturers, repackages the ingredients, and resells them to compounding pharmacies, and also sells bases into which those active pharmaceutical ingredients are added. *Id.*, ¶ 2. PCCA also reports the AWPs of certain products to commercial publishers of drug pricing data for each active pharmaceutical ingredient and base it sells. *See id.*, ¶ 53.

PCCA customer pharmacies then create and dispense the physician-prescribed compounded pharmaceuticals themselves and submit the claims for payment. *See id.*, ¶ 52. As the government's Complaint recognizes, PCCA cannot and "does not itself submit claims to TRICARE." *Id.*, ¶ 52.

II. PCCA has never made or sold, and does not currently make or sell, a product covered by any federal healthcare program, including TRICARE.

The government does not and cannot allege that any product ever sold by PCCA was eligible for reimbursement by any federal program, including TRICARE. TRICARE, like other federal programs, only covers prescription medications that are FDA approved. *See* 32 CFR § 199.21. Active pharmaceutical ingredients are FDA registered but not FDA approved, and thus cannot be submitted for TRICARE reimbursement. PCCA is not a pharmacy nor a provider: a patient could never come to PCCA to ask for a container with, for example, gabapentin powder; PCCA could never bill any third party insurer, federal or otherwise, for a sale of gabapentin powder; and PCCA could never fill a prescription of any patient. In fact, as a result, PCCA is not even eligible for a supplier number from any federal program or insurer.

More importantly, compounded medications that are compounded using active pharmaceutical ingredients are themselves not covered by any federal program, including TRICARE.[1] This is for the same reason that PCCA's products themselves are not covered – such compounded medications containing PCCA products are not FDA approved. In short, PCCA's products are not covered by TRICARE and neither are compounded medications containing them.

III. AWP is not defined in the government's Complaint and had no material statutory or regulatory definition during all times relevant to the government's Complaint.

At no point in the government's Complaint does it plead any definition of AWP. **This is fatal to its Complaint**. It makes numerous references to PCCA's AWPs and their correlation (or lack thereof) to average acquisition costs. *See, e.g.*, Dkt. 66, ¶ 1. But at no point does it allege or describe how or why this correlation is meaningful, and in fact courts have found that this

[1] As discussed in more detail below, by no later than July 2012, TRICARE has publicly acknowledged it knew that compounds containing bulk powders were not covered under its regulations and that its payment of claims for such compounds exceeded its regulatory authority. Ex. A. at 19.

correlation is wholly meaningless. *See, e.g.*, *State of La. v. U.S. Dep't of Health & Hum. Servs*., 905 F.2d 877, 880 (5th Cir. 1990) (finding the HHS Secretary rejected using AWP because "AWP data are frequently inflated" and should not be equated with estimated acquisition costs (quoting 40 Fed. Reg. 34518 (Aug. 15, 1975)); *Commonwealth v. TAP Pharm. Prod., Inc.*, 94 A.3d 350, 353 (Pa. 2014) ("By 1991 [*i.e.*, for the past 30 years], there was a wealth of information available to state officials and to the public at large confirming that AWPs served as a 'list' or 'book' price, so that the term 'average wholesale price' was (or had become) a misnomer."); *see also Sandoz Inc. v. Com. ex rel. Conway*, 405 S.W.3d 506, 511 (Ky. Ct. App. 2012) ("The protection of spread through inflated AWPs was endemic in the system, and states across the nation were aware that pharmaceutical companies were reporting bloated AWPs. Further, the Commonwealth itself commissioned a private study of AWP and discovered that AWP was significantly inflated . . . Clearly, the Commonwealth was aware that AWPs were not the actual prices paid for generic drugs.").

The government's own allegations in this case demonstrate clearly how nonsensical any assertion in its Complaint tying AWP to average acquisition cost must be. The government chose, after careful consideration, and a six-plus year investigation, to identify March 2012 as the date on which PCCA's AWPs became "fraudulently inflated." Dkt. 66, ¶ 72. This is because, as alleged by the government, PCCA increased some of its products' AWPs at this time. *Id.* The "AWP Marketplace," (*see id.*, ¶ 73 and Dkt. 66-5) had dictated a raise in the AWP for (for instance) Fluticasone Propionate from $1,500 to $3,325, a 121.67% increase in AWP on a drug the government alleges had an average acquisition cost of $135-$196.82. Dkt. 66, ¶ 61. This is an increase in PCCA's AWP to be sure, and one the government says led to "reimbursement amounts

that were hundreds, and often times thousands, of dollars more than what they actually paid to acquire the underlying ingredients." *Id.*, ¶ 64.

The government wholly fails to include any allegation that would explain, much less a formal regulatory or statutory definition that would dictate, its stated position that an AWP that is 3000% of an active pharmaceutical ingredient's acquisition cost is "fraudulently inflated" while one that is 1500% of that acquisition cost is not fraudulent. Clearly, if average acquisition cost is a metric by which AWP can be measured, the government has pleaded no plausible basis for the Court or PCCA to use it. The government's Complaint is devoid of any objective definition of AWP found in statutory or regulatory law, or even any non-binding agency guidance defining AWP, because no such definition existed at any point relevant to its Complaint. The government's failure to plead an objective standard of AWP is fatal to its Complaint.

IV. The government, TRICARE, and ESI were well aware that AWPs were being inflated by suppliers and that AWP had no meaningful definition.

There is no reasonable dispute that by the relevant time period alleged in the Complaint, the government clearly understood that AWP was different from average sales price and was not reflective of actual processes in the marketplace. One court found, relying upon a Fifth Circuit opinion, that the public, including state officials, had a wealth of information available, ***by 1991***, that confirmed that AWPs served as a "list" or "book" price such that the term "average wholesale price" had become a misnomer. *TAP Pharm. Prod., Inc.*, 94 A.3d at 353 (citing *State of La.,* 905 F.2d at 880). The government's long established knowledge of these facts show that they were not material to TRICARE's ultimate decision to pay claims. As discussed more fully below, in 2012, the government was aware of and declined to intervene in an FCA case against TRICARE's contractor for adjudicating claims, alleging, in part, that Express Scripts, Inc. ("Express Scripts"

or "ESI") improperly profited from the knowing inflation of AWPs on prescription pharmaceuticals.[2]

V. The government implemented D.0 as a reimbursement model and reimbursed compounds containing non-FDA approved products, knowing that doing so violated its own regulations.

On January 1, 2012, in order to receive reimbursement, the government adopted the National Council for Prescription Drug Program ("NCPDP") D.0 Standard for reimbursement under the TRICARE Program. *See* Dkt. 66, ¶ 43. Pursuant to D.0, TRICARE received information on and began reimbursing for all ingredients in a compound, not just the most expensive ingredient. *See id.*, ¶ 44. In contravention of its own regulations, this included reimbursement for ingredients sold by PCCA. *See* 32 CFR § 199.21.

The government elected to rely on AWP in reimbursement of these non-covered items under D.0, even though TRICARE and ESI knew that such items were not covered **and** that AWP was an undefined concept. *See* Dkt 66, ¶ 45. According to the government's allegations, which are pled in "general[ities]," TRICARE, *via* ESI, reimbursed prescription medications on the lesser of the following reported amounts: "(1) the sum total of the AWPs (minus a contracted discount)[3] for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; (2) the sum total of the costs submitted by the pharmacy for all ingredients in the compound drug, plus a dispensing fee and level of effort fee; or (3) the pharmacy's usual and customary charge for the medication."

[2] In fact, as argued below, the government was aware of these allegations, declined to intervene in the fraud case against ESI, and the Court ultimately found that the inflation of AWPs was such a commonly understood fact that the case should be dismissed under the public disclosure bar. *See U.S. ex rel. Morgan v. Express Scripts, Inc.,* 2013 WL 6447846, at *9 (D.N.J. 2013) (quoting an article in the Wall Street Journal that it was "'an open secret in the industry that AWPs are often severely inflated' and that PBMs attempted to 'take advantage of the "spread" between pharmacy prices and what corporate and government clients pay.'").

[3] The government's Complaint does not specifically allege the Provider Agreement's discount off AWP or that the discount is the same for all pharmacies.

Id., ¶ 45. While the government's Complaint alleges a definition for "usual and customary" price ("U&C"), the Complaint is silent on the definition of AWP. *See id.*, ¶ 46.

In early 2012, it became clear to PCCA that its competitors were increasing their AWPs in response to the change in reimbursement. *See id.*, ¶ 66. PCCA initially resisted its customers' requests for it to follow suit. *See id.* In fact, PCCA felt following such a path would not be "good strategy." *Id.*, ¶ 67. Notably, because the government provided no definition or other guidance on what AWP was, PCCA turned to the only standard by which it could measure AWP – its competitors in the market. *Id.*, ¶ 69. Only after the market rate for AWPs on its products increased did PCCA begin to raise its AWPs, and, per the government's allegations, only to market rates already set by its competitors. *See* Dkt. 66 at ¶¶ 65-72, Ex. 4 ("[G]iven that [redacted] has become a key competitor for the business of our members who bill insurance, our position will be to follow their list of products and pricing to compete with their offering.").

ARGUMENT

I. Legal Standard.

A. Rule 12(b)(6) Standard.

To survive a motion to dismiss, a complaint "must provide the plaintiff's grounds for entitlement to relief – including factual allegations that when assumed to be true 'raise a right to belief above the speculative level.'" *U.S. ex rel. Porter v. Magnolia Health Plan, Inc.*, 810 Fed.App'x 237, 240 (5th Cir. 2020) (quoting *Cuvillier v. Taylor*, 503 F.3d 397, 401 (5th Cir. 2007)). A motion under Rule 12(b)(6) "must be read in conjunction with Rule 8(a) of the Federal Rules of Civil Procedure." *U.S. ex rel. Reddell v. DynCorp Intl., LLC*, Civil Action No. 1:14-CV-86, 2019 WL 12875471, at *3 (E.D. Tex. Sept. 17, 2019). This obligates claimants to plead "enough facts to state a claim to relief that is plausible on its face." *Id.*; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). In assessing the sufficiency of the pleadings, courts "are not bound to

accept as true a legal conclusion couched as a factual allegation." *Iqbal*, 556 U.S. at 679 (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). Accordingly, "conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss." *Aguocha-Ohakweh v. Harris Cty. Hosp. Dist*., 731 Fed. App'x 312, 315 (5th Cir. 2018) (quoting *Beavers v. Metro. Life Ins. Co.*, 566 F.3d 436, 439 (5th Cir. 2009)).

B. Rule 9(b) Standard.

In addition to satisfying Rule 12(b)(6), "[c]omplaints filed pursuant to the False Claims Act must also satisfy the 'heightened' pleading standard of Federal Rule of Civil Procedure 9(b)." *Magnolia Health Plan, Inc.*, 810 Fed.App'x at 240 (quoting *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d. 180, 185 (5th Cir. 2009)). Rule 9(b) requires parties alleging fraud to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A FCA plaintiff must plead, "at a minimum," "the who, what, when, where, and how of the alleged fraud." *U.S. ex rel. Colquitt v. Abbott Lab'ys*, 858 F.3d 365, 371 (5th Cir. 2017) (quoting *Williams v. WMX Tech., Inc*., 112 F.3d 175, 179 (5th Cir. 1997). Courts "apply Rule 9(b) to fraud complaints with bite and without apology." *Grubbs*, 565 F.3d at 185.

C. The Court should take judicial notice of the October 2014 GAO Report on TRICARE's reimbursement of compounded medications including bulk powders and July 2002 GAO Testimony Report on Department of Defense Healthcare Costs.

While courts are generally required to limit their consideration of a motion to dismiss under Rule 12(b)(6) to the allegations contained in the complaint, giving all favorable inferences to the plaintiff, it is within the Court's discretion to take judicial notice of certain types of reliable government documents. *See Miller v. Stroman*, CIVIL NO. 1-19-CV-00475-ADA, 2020 WL 2494576, at *1 (W.D. Tex. May 14, 2020) (quoting Fed. R. Evid. 201(b); *Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011)); *see also DynCorp Intl, LLC*, 2019 WL 12875471, at *3 ("The

court may . . . consider matters that are outside the pleadings if those matters are matters of public record."). In some cases, such government documents are essential to the Court's fair determination of the motion to dismiss. *Id.* In particular, where the Court, as here, is considering critical issues of falsity, materiality, knowledge, and causation at the motion to dismiss stage, it is important that the Court understand the proper context of the government's allegations.

PCCA discusses two reports issued by the Government Accountability Office ("GAO") in this Motion that are not specifically mentioned in the government's Complaint.[4] The GAO reports are documents published by the government itself. They are the result of audits conducted by the GAO, an agency expressly authorized and directed to conduct the reviews by Congress, and contain findings concurred with by TRICARE. The facts therein are important for the Court's consideration of the reasonableness of PCCA's conduct. Moreover, they bear heavily on what the government knew in this case and when they knew it. These facts will advance considerably the Court's consideration of the issues raised in this Motion, including the sufficiency of the government's allegations related to falsity, materiality, knowledge, and causation.

The Court should take judicial notice of the GAO report for at least the above reasons. However, the arguments below stand on their own based on relevant legal precedent and the allegations in (and exhibits attached to) the Complaint. The Court can and should dismiss the Complaint regardless of the information in the GAO reports discussed in this Motion. PCCA has endeavored to structure its arguments so that inclusion of references to the GAO reports are additive, but not essential, to its arguments. However, PCCA requests the Court take such notice

[4] In October of 2014, the GAO issued a report to congress titled *COMPOUNDED DRUGS: TRICARE's Payment Practices Should Be More Consistent with Regulations*. *See* Ex. A to the Motion. In July 2002, the GAO issued a testimony report titled *VA and DOD Health Care, Factors Contributing to Reduced Pharmacy Costs and Continuing Challenges*." GAO-02-969T. *See* Ex. B. to the Motion.

of these reports, which is well within the Court's power, and use the context they provide to accurately evaluate the sufficiency of the government's allegations.

II. The Court should dismiss the government's insufficiently pled False Claims Act claims.

Even with over six years to investigate and prepare its Complaint, the government fails to meet its burden to sufficiently plead a viable FCA violation. In hopes the Court will not notice basic FCA requirements missing, the government attempts to distract this Court and glosses over its shortcomings by misstating the scope of the FCA, ignoring the legal framework and context underlying its claims, and relying upon bald conclusory assertions insufficient to withstand a motion to dismiss. Allowing this Complaint to survive dismissal would be a miscarriage of justice and expand the FCA beyond recognition, beyond predictability, and beyond the parameters laid out by the U.S. Supreme Court. After over six years and the filing of a wholly deficient Complaint, dismissal is warranted and necessary.

A. The government's Complaint should be dismissed because it fails to allege falsity as required under 31 U.S.C. § 3729(a)(1)(B).

The government alleges that by reporting "false" AWPs to commercial pricing compendia, PCCA violated the FCA. In this Court, falsity of such statements must be objectively measurable against some standard. *U.S. ex rel. Barron v. Deloitte & Touche, LLP*, Civil No. SA-99-CA-1093-FB, 2009 WL 10670806, at *13 (W.D. Tex. Feb. 11, 2009) (stating that "[t]o prevail on …FCA claims, [a claimant] must demonstrate … that a claim was '**objectively false**[.]'") (emphasis added), *report and recommendation adopted*, 2009 WL 10670807 (W.D. Tex. Mar. 26, 2009); *see also U.S. v. AseraCare, Inc.*, 938 F.3d 1278, 1298, n.11 (11th Cir. 2019) (holding "the Government must show an objective falsity."); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 376 (4th Cir. 2008) ("To satisfy [the] first element of an FCA claim, the statement or conduct alleged must represent an objective falsehood."); *U.S. ex rel. Long v. GSD & M Idea City LLC*,

Civil Action No. 3:11-cv-1154-O, 2013 WL 214590, at *7 (N.D. Tex. Jan. 18, 2013) ("In order to allege an FCA claim, the statement or conduct alleged must represent an objective falsehood."); *U.S. ex rel. DRC, Inc. v. Custer Battles, LLC*, 472 F.Supp.2d 787, 797 (E.D. Va. 2007) ("It is well-established that the FCA requires proof of an objective falsehood."), *aff'd*, 562 F.3d 295 (4th Cir. 2009). Therefore, the government must allege statements or conduct that are capable 'of being adjudged true or false in a way that … admits empirical verification.'" *U.S. ex rel. Dekort v. Integrated Coast Guard Sys.*, 705 F.Supp.2d 519, 533 (N.D. Tex. 2010) (quoting *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 792 (4th Cir. 1999). Presentment of a false claim to the government "is the *sin qua non* of a False Claims Act violation []."*Grubbs*, 565 F.3d at 186. The "paradigmatic" false claim is "an incorrect description of the goods or services provided or a request for reimbursement for goods or services never provided." *U.S. ex rel. McBride v. Halliburton Co.,* 848 F.3d 1027, 1031 (D.C. Cir. 2017) (internal citations omitted).

The government's entire Complaint is based on an allegation that the AWPs reported by PCCA were **false**. Inasmuch, the government repeatedly refers to PCCA's AWPs as false, fraudulent, and fraudulently inflated. The government alleges that PCCA's AWPs created mega-spreads. However, such generic allegations of falsity are not enough to overcome the standard imposed under Rule 9(b) in this Court. The government does not define AWP in its Complaint, nor does it point to any statutory or regulatory authority defining it. However, the use of legal terms of art like "false" and "fraudulent" have no more meaning when applied to the concept of AWPs than they would if the government called a mango "fraudulently inflated." Without offering a clear definition as to what "fraudulently inflated" means, the only fair inference to be drawn is that it is just a mango. Such broad allegations are not sufficient to meet the particularity standard set by Rule 9(b).

PCCA's average acquisition price would not be such an objective measure for the reasons explained above. The government provides no legal authority for using it as such an objective measure. The government's allegations also fail to explain how, if average acquisition cost is an objective measure of AWP, it is fraudulent to report AWPs at 3,000% of that cost, as PCCA is alleged to have done after March 2012 but appropriate to set AWPs at 1,500% of that cost, as PCCA is alleged to have done prior to March 2012. Without explanation, this result is nonsensical and not a reliable basis by which the Court can measure AWP. In fact, because no meaningful statutory or regulatory definition of the term is pleaded (and none existed at the time), companies like PCCA operating in the market were similarly without guidance.

Moreover, the government alleges that PCCA reported its AWPs to "commercial publishers of drug pricing data," "publishers of pharmaceutical pricing data, such as Medispan," and "commercial pricing compendia" throughout its Complaint. Dkt. 66, ¶¶ 2, 53, 186. The Complaint further alleges that "[t]hose publishers reported PCCA's AWPs in pricing compendia available to federal health care programs, private insurance companies, and other purchasers of prescription drugs." *Id.*, ¶ 54. So, in this case, the alleged false statements were not made directly to TRICARE or the government more broadly, but rather to third-party publishers to be included in publicly available pricing compendia. The government does not plead whether these third parties had standards for reporting AWP, what those standards were and whether they aligned with TRICARE coverage regulations. It is appropriate to infer that like other publishers, these publishers had their own standards for reporting and publication of data with which PCCA complied. If you make a truthful statement to a third party that the government relies on to its detriment, that is not a false statement to the government. Without having pleaded whether such standards exist and what they are, the government has further failed to plead an objective basis by

which the Court can judge falsity. Because the government has failed to plead objective falsity, its Complaint should be dismissed.

B. The Court should dismiss the government's Complaint because it does not sufficiently tie the PCCA's alleged misconduct to any actual claims.

"The False Claims Act does not create liability merely for a health care provider's disregard of government regulations or improper internal policies unless, as a result of such acts, the provider knowingly asks the government to pay amounts it does not owe." *U.S. ex rel. Willard v. Humana Health Plan of Texas Inc.,* 336 F.3d 375, 381 (5th Cir. 2003) (quoting *Harrison*, 176 F.3d at 785) ("The statute attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the 'claim for payment.' . . . Therefore, a central question in False Claims Act cases is whether the defendant ever presented a 'false or fraudulent claim' to the government."). Here, the government has alleged that PCCA falsely reported inflated AWPs to third-party publishers, and that those falsely reported AWPs were material to false and fraudulent claims paid by TRICARE. Dkt. 66, ¶ 186. However, with respect to those claims, the government has not adequately described why or how the claims submitted were false or fraudulent.

Firstly, the government does not plead that any of the claims referenced in Exhibit 22 of its Complaint were submitted and paid based on the AWP for the ingredients listed. That chart lists only the reimbursement amount, the ingredient name and the ingredient National Drug Code ("NDC"). *See* Dkt. 66-22. The government alleges that the 325 claims contained in Exhibit 22 are "inflated," but at no point alleges that those claims were inflated because they were reimbursed based on PCCA's AWPs. Dkt. 66, ¶ 123. In fact, the government alleges two other bases for reimbursement of medications under TRICARE – the U&C or relevant pharmacy costs – neither of which is listed in Exhibit 22. The government alleges that reimbursement "was frequently

determined by the reported AWPs" but also alleges that U&C for many compounded medications[5] were lower than final compounded products AWP and that U&C was set and reported by PCCA's customers, not PCCA. *Id.*, ¶ 117. If the Court credits the government's allegations, as it must, then presumably many claims submitted using PCCA's products should have been based on U&C or the relevant pharmacy costs allowed under statute, both of which were alleged to be required to be reported for a claim to TRICARE to be payable.

Exhibit 22 does not list the reported AWP, nor the reported U&C, nor the reported pharmacy costs for any of the claims listed within it. The Court should not infer what the government is otherwise required to plead and the Complaint's allegations do not satisfy 9(b)'s requirement to tie the generally alleged fraudulent conduct of PCCA setting market AWPs to specific claims submitted by unidentified pharmacies. *See Clark v. Thompson*, 850 Fed.App'x 203, 206 (5th Cir. 2021) (stating that where "the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'show[n]'—that the pleader is entitled to relief.") (citations omitted; alteration in original); *Brooks v. U.S. Dep't of Veterans Affairs*, Case No. 20-cv-23114-BLOOM/Louis, 2021 WL 76200, at *2 (S.D. Fla. Jan. 8, 2021) ("Moreover, courts may infer from the factual allegations in the complaint obvious alternative explanations, which suggest lawful conduct rather than the unlawful conduct the plaintiff would ask the court to infer.") (citations and internal quotation marks omitted). The government's Complaint should be dismissed because it fails to tie the specific claims it identifies with sufficient particularity to PCCA's AWPs.

[5] The government alleges that U&C is the "usual and customary retail price of a covered medication in a cash transaction at the dispensing pharmacy." Dkt. 66 at ¶46. As discussed in detail throughout this Motion, the compounded medications at issue in this case were not "covered medication[s]" and thus the concept of U&C would not be applicable to the compounded medications containing PCCA products. Moreover, no pharmacy dispenses any PCCA product as a standalone medication, and as such no pharmacy would have a U&C price for any PCCA product.

This problem is further compounded by the government's failure to plead a standard by which AWP can be properly measured. Specifically, the government does not allege that any claim covered by its Complaint was for medically unnecessary services. Thus, the Court can only infer that some portion of these claims was legitimately reimbursed and the government has not alleged which portion was improper, nor given the Court a general basis for making such a determination. A fair inference should be drawn by the Court that it is possible some of the specific claims identified by the government, even if based on PCCA's AWPs, were wholly appropriate. The government refers to the claims as "inflated," but does not explain how or why they are inflated, or what portion of the 325 claims it identifies was not appropriately reimbursed. Without particular pleadings related to how, why, and how much of any specific claims were fraudulent (much less that reimbursement for such claims was based on PCCA's AWPs in the first place), PCCA is not on sufficient notice of what specific claims, and what specific portions of those claims, are alleged to be fraudulent.

In an FCA case, the government must not just plead a general fraud scheme, but must also plead "reliable indicia that lead to a strong inference that claims were actually submitted." *Grubbs*, 565 F.3d at 190. For instance, the government must both allege "a scheme to submit false claims and details leading to a strong inference that those claims were submitted – such as dates and descriptions of record, but unprovided services and a description of billing systems that the records were likely entered into – [that] gives defendants adequate notice of the claims." *Id.* Here the government's pleadings are deficient in this regard both because they fail to provide specific details showing specific claims were actually reimbursed on the basis of AWP and because it fails to put PCCA adequately on notice of what standard it is alleging should have been used for setting AWP. And while the Court is entitled under *Grubbs* to give the government some leeway on how the

falsity of specific claims is described, *Grubbs* is at least clear that the Court cannot just take the government's word for it. Because it fails to specify the basis for reimbursement for, and how and in what measure any claim or set of claims was false, the government's Complaint fails under Rule 9(b)'s heightened pleading requirement and should be dismissed.

C. The Court should dismiss the government's Complaint because it does not identify any certification, express or implied, that was false.

The government alleges two bases for the submission of false claims allegedly cause by PCCA in its Complaint: the reporting of false AWPs to third-party publishers and the payment of kickbacks. The government acknowledges that to prove either of its theories it must show some false certification, in this case an implied false certification, of compliance with regulations or contractual obligations. Dkt. 66, ¶ 26. When "the government has conditioned payment of a claim upon a claimant's certification of compliance with, for example, a statute or regulation, a claimant submits a false or fraudulent claim when he or she falsely certifies compliance with that statute or regulation." *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 902 (5th Cir. 1997). These "false certifications of compliance create liability under the FCA when certification is a prerequisite to obtaining a government benefit." *Id.*

The false certification can be either express or implied: for express certification, the government must show that a particular claim made for payment contained an express certification that falsely certified compliance with certain requirements. *See U.S. ex rel. Landis v. Tailwind Sports Corp.*, 234 F.Supp.3d 180, 197 (D.D.C. 2017). For implied certification, the government must at least plead that the defendant submitted claims to the government for payment that made "specific representations about the goods or services provided[.]" *Universal Health Svcs., Inc. v. U.S. ex rel. Escobar*, 579 U.S. 176, 190 (2016).

First and foremost, after its explanation that claims can arise out of express or implied certifications in Complaint Paragraph 26, the government never bothers to plead any certification at all. PCCA is not and never has been itself a "claimant" to the government. PCCA does not have and cannot obtain a billing number to directly bill TRICARE. It is not bound by ESI's provider manuals, and it has no legal obligation to abide by either TRICARE's reimbursement policies or the AKS because the products it sells are not covered items. Again, no patient ever receives a PCCA product – they receive a pharmacy compounded product. The government has generally pleaded that PCCA knew that its AWPs were material to TRICARE's reimbursement decisions. However, it has not pleaded that PCCA ever certified that its AWPs were accurate, or that they were somehow true or correct by any standard pleaded.

In fact, PCCA is not obligated by TRICARE regulations to report AWPs at all, as it does not manufacture, produce or sell any covered product. The Complaint simply states broadly that PCCA's AWPs were "fraudulently inflated" and hopes the Court's imagination will do the rest of its work. However, no reading of Rule 12(b)(6), no matter how generous, allows the Court to infer a certification that is not alleged. *See, e.g., Harrison*, 176 F.3d at 793 ("[The FCA] claim fails on the pleadings because [the relator] has never asserted that such implied certifications were in any way related to, let alone prerequisites for, receiving continued funding."). Because the Complaint fails to allege the contents of a single claim for payment or any relevant certification, the Complaint is categorically deficient as to this theory and should be dismissed. *See, e.g., Martin v. Arc of Dist. of Columbia*, 541 F.Supp.2d 77, 83 (D.D.C. 2008) ("[T]he complaint … fails to provide any of the purported details such as the time, place, and contents of the alleged false representation.").

The government alleges that a violation of the AKS is a per se violation of the FCA, thus suggesting that its AKS theory of liability is not premised on any implied certification theory.

However, recent precedent from this District indicates that a certification, express or implied, is still required to establish liability under the FCA for an AKS violation, even though an AKS violation may be an FCA violation as a matter of law. *See U.S. v. Marlin Med. Sols. LLC*, CIVIL NO. SA-21-CV-00160-OLG, 2022 WL 190308, at *3 (W.D. Tex. Jan. 12, 2022). In discussing the interplay between the AKS and FCA, Chief Judge Garcia quoted *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 Fed.App'x 890, (5th Cir. 2013) holding "[a] violation of the AKS can serve as the basis for a FCA claim when the government has conditioned payment of a claim upon the claimant's certification of compliance with the statute, and the claimant falsely certifies compliance." *Id.* Thus, it is incumbent upon the government to plead, with particularity an express or implied certification that PCCA made or caused to be made, both with respect to the accuracy of its AWPs and with respect to its compliance with the AKS.

As with PCCA's reporting of AWP, the government's Complaint makes no allegation of any certification of compliance with the AKS of which PCCA was aware – either made by it or by one of its customers. The Complaint does not even allege that PCCA was aware of the existence of the AKS. While proving an AKS violation does not require proof that PCCA knew about the AKS, proof of an FCA violation does require proof of a knowing false certification of compliance with it. *See Marlin Medical*, 2022 WL 190308, at *3. Nowhere in its Complaint, which was six years in the making, does the government allege such a certification. For this reason, the government's Complaint should be dismissed.

D. The Court should dismiss the government's Complaint because it fails to properly plead materiality.

"[A] false or fraudulent claim violates the FCA only if the misrepresentation it contains is material." *U.S. ex rel. Montcrieff v. Peripheral Vascular Assocs., P.A.*, 507 F.Supp.3d 734, 758 (W.D. Tex. 2020) (quoting *Waldmann v. Fulp*, 259 F.Supp.3d 579, at 589-90) *on reconsideration*

in part, 2022 WL 80293 (W.D. Tex. Jan. 7, 2022). Under the Supreme Court's ruling in *Escobar*, the government's decision to continue reimbursing compounding claims despite knowledge of the conduct it now claims was fraudulent requires dismissal. *See Escobar*, 579 U.S. at 195. Stated another way, the government and its agent, Express Scripts, were aware the reported AWPs bore no relation to acquisition cost and were aware of the alleged non-compliant conduct, and *still* continued to reimburse pharmacy claims based on PCCA's reported AWPs. Accordingly, the government's FCA claims should be dismissed for want of materiality.

Furthermore, the government's Complaint also fails to establish materiality on a purely fundamental level. Common sense dictates that AWPs reported on products that TRICARE **does not cover** should not be material to any reimbursement decision it makes. To the extent the government argues that PCCA's AWPs were material to such decisions, it would only be because TRICARE knowingly and intentionally violated its own regulations in reimbursing pharmacies for compounds containing PCCA's ingredients. Ex. A at 2; *see also* Dkt. 66, ¶ 169. According to TRICARE's regulations, PCCA's AWPs should not have been material to any payment decision and the agency's choice to violate its own procedures does not, somehow, make its reimbursement of those items authorized. In other words, just because TRICARE may have taken PCCA's AWPs into consideration when determining reimbursement amounts, it did not have legal authority to do so.

As such, the government's Complaint should also be dismissed for failing to establish materiality.

1. Courts routinely dismiss cases where the government continued to pay claims despite knowledge of the alleged misconduct.

The government's Complaint fails to adequately plead materiality in a number of critical ways. To be actionable under the FCA, an alleged misrepresentation "must be material to the

Government's payment decision in order to be actionable under the False Claim Act." *Escobar*, 579 U.S. at 192. The FCA defines information as material if it has a "natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). Importantly, however, the "False Claims Act is not 'an all-purpose antifraud statute' . . . or a vehicle for punishing garden-variety breaches of contract or regulatory violations." *Escobar*, 579 U.S. at 194.[6]

In the unanimous *Escobar* opinion, the U.S. Supreme Court emphasized that the materiality standard is intentionally "demanding" and "rigorous." *Id.* at 171, 181, 194; *Montcrieff*, 507 F.Supp.3d at 758 (finding the FCA "materiality requirement is a 'rigorous' one.") (*citing Escobar*, 579 U.S. at 181)), *on reconsideration in part*, 2022 WL 80293 (W.D. Tex. Jan. 7, 2022). The Supreme Court further emphasized that the materiality standard is not "too fact intensive" for courts to resolve on a motion to dismiss. *Escobar*, 579 U.S. at 195 n.6. *See also, e.g.*, *U.S. ex rel. Nargol v. DePuy Orthopedics, Inc.*, 865 F.3d 29, 34 (1st Cir. 2017) (affirming dismissal of FCA claim because the FDA's decision not to withdraw its approval after learning of the alleged violations "render[ed] a claim of materiality implausible"); *D'Agostino v. ev3, Inc.*, 845 F.3d 1, 7 (1st Cir. 2016) (affirming dismissal of FCA complaint because "the FCA requires that the fraudulent representation be material to the government's payment decision" and the Government's continued reimbursement of purchases "in the wake of [the plaintiff's] allegations casts serious doubt on the materiality of the [alleged] fraudulent representations"); *U.S. ex rel. Thomas v. Black & Veatch Special Projects Corp.*, 820 F.3d 1162, 1165-66, 1172, 1174 (10th Cir. 2016) (plaintiff's contentions were "simply incapable" of showing materiality where after learning

[6] The government's claim that "[t]he FCA is intended to reach all types of fraud, without qualification, that might result in financial loss to the government" is simply false and the type overreaching application the U.S. Supreme Court sought to curtail. *Compare* Dkt. 66, ¶ 25, *with Escobar*, 579 U.S. at 194.

of the alleged violation, the government never withheld payment); *U.S. ex rel. Patel v. Catholic Health Initiatives,* 792 Fed.App'x 296, 301 (5th Cir. 2019)(finding that the relators failed to adequately plead materiality where they presented no allegations to suggest that the government would have stopped paying claims had it known of the violation); *U.S. ex rel. Porter v. Centene Corp.*, CIVIL NO. 1:16cv75-HSO-JCG, 2018 WL 9866507, at *4-6 (S.D. Miss. Sept. 27, 2018), *aff'd*, 810 Fed.App'x 237 (5th Cir. 2020) (dismissing FCA complaint for lack of materiality where plaintiff solely alleged misrepresentation of compliance with a statutory, regulatory, or contractual requirement as a condition of payment and government "continued payment and renewed its contract with [defendant] several times."); *U.S. ex rel. Marshall v. Woodward, Inc.*, 812 F.3d 556, 563 (7th Cir. 2015) (affirming dismissal of FCA complaint for lack of materiality where government continued payments after investigation of plaintiff's concerns). *Cf. U.S. ex rel. LaCorte v. SmithKline Beecham Clinical Labs., Inc.*, 149 F.3d 227, 234 (3d Cir. 1998) ("[O]nce the government knows the essential facts of a[n allegedly] fraudulent scheme, it has enough information to discover related funds.").

In *Escobar*, the U.S. Supreme Court specifically rejected the government's argument that a misrepresentation is material just because it goes to a condition of payment. *See* 579 U.S. at 190 (Curtailing the governments expansive use of the FCA and holding "[n]ot every undisclosed violation of an express condition of payment automatically triggers liability"). To establish materiality, the government must have specific and particularized evidence beyond statutory, regulatory, or contractual requirements. *See id.* at 188.

In cases where the government alleges that claims presented are not factually false, but rather legally false (meaning they do not comply with a particular statue, *i.e.* implied certification), "materiality looks to the effect on the likely or actual behavior of the recipient of the alleged

misrepresentation." *Id.* at 193 (internal citation omitted). Courts reviewing the sufficiency of pleadings, therefore, look for specific facts reflecting whether the government's payment decision would likely have been different if the government knew about the alleged misconduct. *Id.*

Importantly, the government fails to establish materiality where "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated," or "the Government regularly pays a particular type of claim despite its actual knowledge that certain requirements were violated." *Magnolia Health Plan, Inc.*, 810 Fed.App'x at 240-241 (quoting *Escobar*, 579 U.S. at 195); *Montcrieff*, 507 F.Supp.3d at 765. Therefore, "crucially, 'if the Government regularly pays a particular type of claim despite actual knowledge that certain requirements were violated, and has signaled no change in position, that is strong evidence that the requirements are not material." *Patel*, 792 Fed.App'x at 301 (citing *Escobar*, 579 U.S. at 195). In other words, courts "understand[] materiality to turn on whether the government would pay the claim or not if it knew of the claimant's violation." *Id*.

Following *Escobar*, courts routinely dismiss claims when the government knows of the violation of certain requirements and continues to pay claims. *See, e.g.*, *U.S. ex rel. Berg v. Honeywell Intl, Inc.*, 740 Fed.App'x 535 (9th Cir. 2018) (affirming summary judgment dismissal where the Army continued to pay Honeywell's claims despite being aware of the FCA case); *U.S. ex rel. Kelly v. Serco, Inc.*, 846 F.3d 325 (9th Cir. 2017) (no materiality existed because the "possibility the government would be entitled to refuse payment if it were aware" of the "alleged violations by itself is insufficient" and because the government did accept Serco's reports "despite their non-compliance"); *U.S. ex rel. Hartpence v. Kinetic Concepts, Inc.*, Case No. 2:08-cv-01885-CAS-AGR, 2019 WL 3291582 (C.D. Cal. June 14, 2019) (no materiality where the government continued to pay despite knowledge of the alleged improper billing practices from pre-payment

and post-payment audits); *U.S. ex rel. Kolchinsky v. Moody's Corp.*, 238 F.Supp.3d 550 (S.D.N.Y. 2017) (no materiality existed where credible public reports of inaccuracies spawned inquiries by the federal government, but "the government has nonetheless continued to pay"). Simply put, courts "should not ignore what actually occurred" and should take into account that the government has in fact continued paying claims despite knowing of the fraud allegations. *Halliburton Co.*, 848 F.3d at 1034.

2. The government knew the details of the alleged misconduct and continued to pay.

a. The government knew AWP represented a sticker price bearing no relationship to the actual sales or purchase price, but reimbursed claims anyway.

The government knows that the publicly reported AWPs, as commonly applied and understood during the relevant time period, were not representative, related to, or reflective of an estimated acquisition costs. *See, e.g.*, *State* of *La.*, 905 F.2d at 880 (finding the HHS Secretary rejected using AWP because "AWP data are frequently inflated" and should not be equated with estimated acquisition costs) (quoting 40 Fed. Reg. 34518 (Aug. 15, 1975)); *TAP Pharm. Prod., Inc.*, 94 A.3d at 353 ("By 1991 [*i.e.*, for the past 30 years], there was a wealth of information available to state officials and to the public at large confirming that AWPs served as a "list" or "book" price, so that the term "average wholesale price" was (or had become) a misnomer.") (citing *State of La.,* 905 F.2d at 880). The government concedes in its Complaint that it was aware by at least 2003 that AWPs were often "manipulat[ed.]" Dkt. 66, ¶ 37. Further, in the case cited immediately above and those cited below, the government was a party to any number of lawsuits where Courts identified the amorphous and ambiguous concept of AWP.

Notwithstanding, in 2012, the government mandated the D.0 Standard and required a reimbursement model based, at least in part, on AWP. *Id.*, ¶¶ 44-45. It did this knowing AWP was

not reflective of actual sale or acquisition price. Even more galling, despite its knowledge that AWPs are often "inflated" (to use the undefined government alleged term), the government did not define AWP for purposes of reimbursement of any medication, much less compounded medications with bulk ingredients including bulk powders which it was not even authorized to cover.

Moreover, GAO 02-969T makes clear that the government knew AWPs were a "list price," "sticker price," or "suggested retail price" not defined in law or by regulation, and that "the manufacturer is free to set an AWP at any level, regardless of the actual price paid by purchasers." Ex. B. Despite years of litigation and public guidance from the government regarding AWP, TRICARE opted to implement a reimbursement model that relied on AWP **and did not define that term or provide any objective basis for calculating or reporting it.**

A global view of the government's conduct shows just how outrageous it really was. The government's conduct in this case could fairly be called super-*Escobar*, because not only did they know of and condone the allegedly inflated reimbursement of compounded medications with bulk substances, it knowingly violated its own regulations to do so.

Though the legal precedent and allegations in the Complaint are sufficient to allow the court to determine that *Escobar's* rigorous materiality standard is not met in this case, PCCA encourages the Court to take judicial notice of the GAO report addressed above.[7] It is essential to understanding the full context of the government's conduct in this case, and it is a reliable source for the Court to rely on because it is the government's own document.

[7] *Stroman*, 2020 WL 2494576, at *1; *Funk*, 631 F.3d at 783; *see also DynCorp Intl, LLC*, 2019 WL 12875471, at *3.

b. The government's agent, Express Scripts, knew and even argued AWP represented a sticker price bearing no relationship to the actual sales or purchase price, but reimbursed TRICARE claims anyway.

Furthermore, Express Scripts, the government's agent engaged to review, adjudicate, and pay pharmacy claims, knew AWP was nothing more than a sticker price bearing no relationship to actual cost. In the midst of the alleged scheme in this case, Express Scripts was sued under the FCA for allegedly profiting off of the pharmaceutical industry's practice of inflating AWPs. *U.S. ex rel. Morgan v. Express Scripts, Inc.*, Civil Action No. 2:05-cv-1714 (DMC)(JAD), 2013 WL 6447846 (D.N.J. Dec. 9, 2013). The government was aware of and a party to that suit. The theory in *Morgan* was almost identical to the allegations in this case – namely, that drug wholesalers were reporting inflated AWPs to drive up reimbursement for their pharmacy customers in order to boost their own sales. *Id.* at *1. The difference was that the relator also brought claims against Express Scripts and alleged in that case that Express Scripts conspired with pharmaceutical wholesalers and intentionally contracted with government payers to ensure that reimbursement of drugs was based on an inflated source of AWPs. *Id.* at *2.

As part of its argument for dismissing the claim under the public disclosure bar in the *Morgan* case, Express Scripts pointed the Court to "numerous law suits filed between 2002 and 2005" with allegations that Express Scripts was aware of and profited off of inflated AWPs (as well as a number of congressional reports and news media articles). *Id.* at *8. Express Scripts argued that a 2003 Wall Street Journal article was grounds for dismissal under the public disclosure bar because it "quot[ed] industry observers as stating that it is 'an open secret in the industry that AWPs often are severely inflated' and that PBMs attempted to 'take advantage of the 'spread' between pharmacy prices and what corporate and government clients pay." *Id.* at *9.

The *Morgan* court ultimately found "the evidence of prior disclosures presented by Defendants to be persuasive." *Id.* at *10. The Third Circuit, in considering the *Morgan* court's opinion, held that "[t]he District court lacked subject matter jurisdiction because Morgan's allegations were 'based upon the public disclosure of allegations' in the news media, other civil proceedings, and a Congressional report." *U.S. ex rel. Morgan v. Express Scripts, Inc. et al.*, 602 Fed.App'x 880 (3d Cir. 2015). It is notable that the Third Circuit found that Express Scripts' knowledge of and potential illicit profits from inflated AWPs was sufficient to dismiss an FCA case against Express Scripts under the public disclosure bar. It is further notable that the Department of Justice, which is not subject to the public disclosure bar, chose not to intervene in the case. *See Morgan*, 2013 WL 6447846, at *2. Not only did the government not pursue fraud allegations against Express Scripts in a case filed right around the time PCCA's alleged scheme began (2012), but it chose to retain Express Scripts as its pharmacy benefit manager ("PBM") for administering claims, and doubled down on AWP pricing by implementing D.0. It took these steps with respect to compounded medications containing bulk substances even though it was aware that such medications were not covered under its regulations.

Again, this is super-*Escobar*. The government not only knew of the alleged inflated AWPs when it paid the claims at issue in this case, **it knew of the alleged inflated AWPs when it decided how it would reimburse for prescription medications, and chose Express Scripts as its PBM to administer the claims**. Under no fair reading of *Escobar* can such a claim for damages survive its rigid materiality standard, and this case should be dismissed.

c. The government knew of PCCA's alleged misconduct and continued to reimburse pharmacies' compounded medication claims.

When the government stops paying claims and then starts paying claims after it knows about the alleged misconduct, that is classic *Escobar*. That is what happened here.

In 2013, TRICARE stopped paying compound claims because of the "significant increase in costs for compound drugs." Ex. A at 2. The Defense Health Agency ("DHA") reported that the high costs can be attributed to "several factors, including . . . the aggressive marketing of compounded drugs containing [bulk ingredient] substances to providers, and **the high AWP of these [bulk ingredient] substances – which, according to DHA and Express Script officials, have been inflated** by manufacturers of these substances." *Id.* at 17, n.8 (emphasis added). However, even with this knowledge, TRICARE elected to lift the restriction on paying compound claims. *See id.* at 2. Based on *Escobar* and its progeny, the government's affirmative decision to continue to reimburse these claims after it knew of its lack of regulatory authority and the inflation of AWPs warrants dismissal for lack of materiality is proper. *Patel*, 792 Fed.App'x at 301 (courts "understand[] materiality to turn on whether the government would pay the claim or not if it knew of the claimant's violation."). Again, here the government also committed to AWP as a basis for reimbursement with this knowledge and continued to accept and pay claims, notwithstanding.

Government Complaint Exhibit 22 shows clearly that the government continued to pay claims for compounded medications with bulk ingredients long after it knew (a) that it did not have regulatory authority to do so; and (b) that AWPs were often inflated. In 2014, the GAO investigated TRICARE's reimbursement of compounded medications with bulk ingredients. The GAO report listed the top 25 compounded medications including specific bulk ingredients billed to TRICARE in an appendix.[8] Exhibit 22 clearly shows that, even after the issuance of the GAO report in October of 2014 (which TRICARE received in August 2014 and reported it concurred with the findings in September 2014), TRICARE continued to reimburse the exact same compounds identified in the report. *Compare* Dkt. 66-22, *with* Ex. A at App'x II; *see also* Exhibit C.

[8] The GAO concluded, and the Department of Defense agreed, TRICARE and ESI's election to reimburse these compounds in the first place was not consistent with TRICARE's regulations.

By way of example, Exhibit 22 shows that TRICARE reimbursed the eighth listed GAO reported compound on April 29, 2015, after the GAO report was sent to the Department of Defense in 2014. Dkt. 66-22; *see also* Table 1.

Table 1: Examples Showing the government Continued to Reimburse Compounds Explicitly Listed in the GAO-15-64 Report and Included in Complaint Exhibit 22

GAO-15-64 Appendix II at 2 (row 8)	Complaint Sample Claims Dkt. 66-22, at 40 (row 2)	
Compounded drug ingredient combination[3]	Ing. Name	Payment Date
8 Fluticasone propionate powder Levocetirizine dihydrochl powder Base, PCCA pracamac oil Pracasil tm-plus gel base	FLUTICASONE PROPIONATE, LEVOCETIRIZINE DIHYDROCHLOR, BASE, PCCA PRACAMAC OIL, PRACASIL TM-PLUS	04/29/2015

Exhibit C to this Motion contains a comparison showing a number of other instances in the government's representative claims where compounds identified in the GAO report were reimbursed by TRICARE after its concurrence with the GAO's findings. The government fails to plead materiality in its Complaint because it fails to allege facts sufficient to allow the Court to conclude that despite TRICARE's and Express Scripts' knowledge of TRICARE's lack of authority to reimburse compounded medications containing bulk ingredients and of the industry practice of setting high AWPs on those ingredients, TRICARE ever denied a single claim for payment based on the AWP of a compounded medication containing bulk substances. *See, e.g.*, *Honeywell*, 740 Fed.App'x 535 (affirming dismissal where the government continued to pay Honeywell's claims despite the results of its own audits and being aware of the problems with using the infiltration rates used by the contractor).

So little did TRICARE care about its lack of authority and its knowledge of inflated AWPs, that Exhibit 22 shows TRICARE reimbursed a pharmacy's April 2015 claim in September 2017.

Dkt. 66-22, at 40.[9] In other words, TRICARE paid a claim **well after the present action was filed** for a compounded medication containing a bulk substance that was submitted six months after TRICARE had concurred with the GAO's findings. Interestingly, the government's Complaint alleges that the Department of Defense's Pharmacy and Therapeutics Committee had met to discuss recommendations regarding TRICARE's reimbursement of compound claims and that by May 1, 2015, TRICARE implemented an "enhanced electronic screening and prior authorization process for compound prescription claims." Dkt. 66, ¶ 161. Yet, the government alleges that it continued paying claims with which it now takes issue. So, even after this action was filed, even after the government implemented a more stringent review requirement for paying claims for compounded medications, TRICARE kept paying not only the type of claims, **but the actual claims**, that the government alleges in this case were fraudulent.

Given the above, based on the allegations, the government's Complaint fails to meet the demanding and rigorous materiality standard and must be dismissed. *See Escobar*, 579 U.S. at 195-96.

d. The government's Complaint admits it knew the "spread" between the pharmacy's cost of the compound and the submitted AWP reimbursement.

Moreover, to even begin to believe that the government's had no idea that AWPs were inflated above the pharmacy's acquisition costs would require TRICARE and ESI to have

[9] The government's sample claims data (Exhibit 22) also identify eight claims allegedly paid in the year 1900. *See* Dkt. 66-22 at 16-17. This apparent error (the payment dates relate to dispensing dates in 2013) draws into question the validity and quality of data relied upon by the government. The government spent six-plus years investigating PCCA and PCCA does not have the TRICARE claims data upon which the government allegedly relies. Notwithstanding its six-plus years of investigating, it selected a sample of 325 claims and presented those to the Court as part of its Complaint, and there are clear errors in the data that go unexplained. If nothing else, PCCA has grave concerns about the accuracy of the government's allegation of hundreds of millions of dollars in damages if that allegation is based on the same data from which the government hand selected these claims. Put more bluntly, if this is what they determined to be the best claims to represent their six-plus years of investigation, what confidence can PCCA or the Court have in their allegations related to claims more broadly in this case?

reviewed the submitted claims with their eyes closed. This information was disclosed and easily ascertainable from the pharmacy's submitted claims and, therefore, the government's Complaint should be dismissed under *Escobar* because it knew but paid the claim anyway.

The government itself asserts that, for each claim submitted for TRICARE reimbursement, the pharmacies were required to include both (1) the AWP for all the ingredients in the compound and (2) the pharmacy's actual costs paid for all the ingredients in the compound. Dkt. 66, ¶ 45. Therefore, the government had access to the "spread" between the AWP reimbursement the pharmacy sought for the compound and the pharmacies' costs for the ingredients in the compound. Given the government's allegations that the reimbursement was thousands of percent's above the acquisition cost, the inflation between the reported AWP reimbursement and the total pharmacy acquisition cost would be readily apparent to reach the levels alleged by the government.[10]

Given the government's own allegations, the claims submitted by a pharmacy revealed on its face that the AWPs were "inflated" and that AWP bore no relation to the cost of the ingredients the pharmacy paid. Notwithstanding, TRICARE and ESI elected to reimburse the claims. Since the government knew about the alleged misconduct and continued to pay the pharmacies' submitted claims, the Court should dismiss the government's Complaint for lack of materiality for this reason as well. *See Escobar*, 579 U.S. at 195-96.

E. The Court should dismiss the government's Complaint because it fails to adequately allege knowledge.

The government's Complaint should be dismissed because it fails to plead knowledge as required under the FCA. To establish liability under the FCA, the government must show that the defendant "knowingly" presented a false claim. 31 U.S.C. § 3729(a)(1). In the Fifth Circuit, to

[10] It is telling that the government's claims data in Exhibit 22 does not include all the information that was required for reimbursement, including the pharmacy's costs of all the compound's ingredients.

establish the required scienter the government must show that the defendant had "guilty knowledge of a purpose . . . to cheat the Government" or "knowledge or guilty intent." *U.S. ex rel. Taylor-Vick v. Smith*, 513 F.3d 228, 231 (5th Cir. 2008) (internal citations and quotation marks omitted); *see also U.S. v. Science Applications Intern. Corp.*, 626 F.3d 1257, 1271 (D.C. Cir. 2010) ("Strict enforcement of the FCA's scienter requirement will … help to ensure that ordinary breaches of contract are not converted into FCA liability."). The government's Complaint here fails because it does not demonstrate PCCA acted with the requisite scienter.

In the FCA context, "knowing" and "knowingly" require a showing that a defendant:

(1) had actual knowledge of the information;

(2) acted in deliberate ignorance of the truth or falsity of the information; or

(3) acted in reckless disregard of the truth or falsity of the information[.]

U.S. ex rel. Longhi v. U.S., 575 F.3d 458, 468 (5th Cir. 2009); 31 U.S.C. § 3729(b)(1)(A). Although the Rule 9(b) heightened pleading standard does not apply to mental states, which "may be alleged generally," Fed. R. Civ. P. 9(b), a bare assertion of knowledge "devoid of further factual enhancement" is insufficient. *Twombly*, 550 U.S. at 555; *see also Melder v. Morris*, 27 F.3d 1097, 1102 (5th Cir. 1994).

1. The government's Complaint fails to satisfy the Supreme Court's *Safeco* knowledge standard.

"While the FCA lists the range of scienter levels encompassed by 'knowingly,' it does not further define those terms." *U.S. v. Supervalu Inc.*, 9 F.4th 455, 463 (7th Cir. 2021). To define "knowingly," every Circuit to consider the question has adopted the Supreme Court's definition stated in *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47 (2007), in the context of the FCA.[11] Thus,

[11] *Safeco* was not an FCA case, but rather interpreted the term "willfully" as defined in the Fair Credit Reporting Act ("FCRA"). However, under the FCRA willfully had several definitions, the lowest threshold being "reckless

to properly plead scienter in an FCA case, the relator or government must first plead that the defendant's knowledge met the *Safeco* standard, and second that the defendant met one of the definitions set forth in 31 U.S.C. § 3729(b)(1)(A), and "a failure to establish the *Safeco* standard as a threshold matter precludes liability under any of these definitions." *Supervalu*, 9 F.4th at 459.

Although the Fifth Circuit has not explicitly yet adopted the *Safeco* standard in the FCA context, every Circuit to consider the question has answered in the affirmative. *See id.* at 459; *U.S. ex rel. Sheldon v. Allergan Sales, LLC*, 24 F.4th 340, 348 (4th Cir. 2022); *U.S. ex rel. Streck v. Allergan*, 746 Fed.App'x 101, 106 (3d Cir. 2018); *U.S. ex rel. McGrath v. Microsemi Corp.*, 690 Fed.App'x 551, 552 (9th Cir. 2017); *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kan. City, PC*, 833 F.3d 874, 879-80 (8th Cir. 2016); *U.S. ex rel. Purcell v. MWI Corp.*, 807 F.3d 281, 284 (D.C. Cir. 2015). Moreover, the *Safeco* standard is in keeping with existing precedent on scienter in the FCA context from this and other districts in the Fifth Circuit. *See U.S. ex rel. Parikh v. Citizens Med. Ctr.*, 977 F.Supp.2d 654, 684 (S.D. Tex. 2013) (stating "[t]he 'knowingly' requirement builds into the FCA much of the 'breathing room to make reasonable but mistaken judgments about open legal questions,' . . . that a qualified immunity defense provides. As the cases Defendants cite in their response . . . make clear, the *scienter* requirement . . . serves to eliminate the prospect of liability in cases where the legality of the defendant's actions is open to debate.").; *U.S. v. Caremark, Inc.*, No. SA-99-CA-00914-WRF, 2008 WL 11280711, at *2 (W.D. Tex. Aug. 27, 2008) ("Even if there is a legal dispute as to whether network restrictions could be applied to Medicaid reimbursement requests (and the Court is not persuaded that there is), such a dispute is insufficient to find FCA liability as a matter of law. 'Where there are legitimate grounds for

disregard." It is the analysis of reckless disregard upon which Circuits have relied in applying *Safeco* in the FCA context.

disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim.'").

The *Safeco* standard states that a "defendant who acted under an incorrect interpretation of the relevant statute or regulation did not act with reckless disregard if (1) the interpretation was objectively reasonable and (2) no authoritative guidance cautioned defendants against it." *Supervalu*, 9 F.4th at 464. "Authoritative guidance" is defined as either a decision of a federal circuit court or authoritative guidance from the agency itself. *Id.* at 471. A defendant's subjective intent is irrelevant under the Supreme Court's analysis. *Id.* at 464. Moreover, not only must the government carry its burden of proof on these issues, but it must adequately plead them to overcome a motion to dismiss as well. *See McGrath*, 690 Fed.App'x at 551. "*Safeco* covers all three of the scienter standards listed in §3729. When relators cannot establish the standard articulated in *Safeco*, there is no liability under the FCA." *Supervalu*, 9 F.4th at 468.

a. The government's Complaint fails to plead that PCCA's interpretation of the TRICARE regulations or AWP was objectively unreasonable.

In the present case, the government must adequately allege both that PCCA knew claims were being submitted **and** that the claims being submitted were false. Under the *Safeco* standard, the government has failed to allege facts to plausibly answer either question.

i. Under *Safeco* the government fails to plead that PCCA knew that claims were being submitted to TRICARE

PCCA's products were not covered by TRICARE and could not properly be submitted for reimbursement neither directly by PCCA, nor indirectly by its customers after being incorporated into compounded medications. While the government alleges that "TRICARE's Reimbursement Criteria . . . Are . . . Material to the Payment of Compound Prescription Claims," (Dkt. 66 at 39 (Heading J)), including several aspects of TRICARE's regulations related to fraud and abuse, the

government alleges only that such regulations are applicable to "[a]ny provider seeking reimbursement from TRICARE." *Id.*, ¶ 165 This description would not extend to PCCA. Under the *Safeco* standard, PCCA's subjective knowledge and intent are not relevant. *See Supervalu*, 9 F.4th at 468 ("A defendant might suspect, believe, or intend to file a false claim, but it cannot *know* that its claim is false if the requirements for that claim are unknown.") (emphasis in original). In other words, the government's allegation that TRICARE's regulations were material to payment of compound prescription claims is accurate, insofar as those regulations did not, and still do not, allow for payment of such claims.

As a result, PCCA, at the time it is alleged to have committed fraud by the government, could have held a completely, objectively reasonable interpretation of extant TRICARE regulations and other statutory and regulatory authority that the products it sold and compounds containing them were not subject to TRICARE reimbursement (or reimbursement from any federal healthcare program for that matter). As such, it could not have known that any action it took would have resulted in any claim being submitted to TRICARE, because its products were not covered by federal payors. This interpretation is actually supported by the Exhibits to the government's Complaint, because while they talk about third party payors and PBMs, they notably do not mention TRICARE or any other federal payor, except for comments about TRICARE in Exhibits 31 and 32 that are not clearly relevant to the subject matter of this case and occurred near the end of timeframe alleged by the government. Therefore, it is a plausible conclusion from the Exhibits to the Complaint that PCCA set its AWPs knowing that they were relevant to third party reimbursement, and also believing that TRICARE did not cover its products.

The government pleads no facts to overcome or counter this otherwise reasonable interpretation of the then existing law. The government's Complaint states that PCCA knew that

TRICARE was a federal healthcare program. It also states that PCCA was aware that claims for its products were being submitted by compounding pharmacies. However, it does not once allege that PCCA's products, nor the compounded medications they were used to make, were covered by any federal healthcare program, including TRICARE. They cannot allege this, because TRICARE's own regulations are quite clear on the subject of coverage:

> Unproven drugs, devices, and medical treatments or procedures. By law, CHAMPUS can only cost-share medically necessary supplies and devices. Any drug, device, or medical treatment or procedure, the safety and efficacy of which have not been established, as described in this paragraph (g)(15), is unproved and cannot be cost-shared by CHAMPUS except as authorized under paragraph 199.4(e)(26) of this part.
>
> (i) A drug, device, or medical treatment or procedure is unproven:
>
> (A) If the drug or device cannot be lawfully marketed without the approval or clearance of the United States Food and Drug Administration (FDA) and approval or clearance for marketing has not been given at the time the drug or device is furnished to the patient. . . .

32 C.F.R. § 199.4(g)(15)(i)(A); *see* Ex A. The government alleges the relevance of this regulation to its case, but fails to plead how or why it is relevant. PCCA's products were not directly, nor indirectly covered.

Again, PCCA's subjective knowledge and intent, and any allegations relevant thereto, are not relevant under the *Safeco* standard. It is the government's burden at the motion to dismiss stage to plead facts sufficient to plausibly show that PCCA's interpretation was **objectively unreasonable**. *McGrath*, 690 Fed.App'x at 552 ("Moreover, even assuming that the statement 'ITAR controlled' on Microsemi's receipts constituted false representation that Microsemi was in compliance with ITAR, the complaint cannot plead facts sufficient to support an inference that Microsemi knew it had failed to comply with ITAR at the time of the representation because Microsemi's good faith interpretation of the term "disclose."). The government does not do this.

In fact, the government fails to plead that PCCA's products were covered, or how or under what circumstances such coverage would be appropriate. PCCA does not have to take the position now that its interpretation of the law was, in fact, that its products were not covered by TRICARE and, thus, could not result in reimbursement. It is enough that such an interpretation of the then existing, relevant law allows for such a reasonable interpretation, and the government wholly fails to plead facts sufficient to show that such an interpretation was objectively unreasonable.[12]

ii. The government fails to plead that PCCA knew claims submitted by its customers were false.

The government also fails, in not pleading a standard by which AWP can be measured or defined, to adequately plead that PCCA knew (or even could have known) that claims submitted by its customers based on AWPs it reported to third parties were false. The government frequently compares the difference between PCCA's AWPs and the average acquisition costs of its products, but fails at any point to identify any legal significance of that correlation. The government also, and in the most general of ways, summarily calls PCCA's AWPs "false and fraudulent" or "fraudulently inflated."

The D.C. Circuit, in assessing the applicability of *Safeco* in the context of the FCA, expressly rejected comparative evidence as being sufficient to demonstrate an interpretation was not objectively reasonable. *Purcell*, 807 F.3d at 290-91. In *Purcell*, the court was evaluating the sufficiency of evidence of knowledge and the applicability of *Safeco* **after** a jury trial and a finding by the jury of knowledge. Despite evidence put on by the government that the commissions at issue in that case were higher than other commissions the defendant paid, the Court found that the government had not shown the defendant's interpretation of the relevant regulation to be

[12] In fact, the GAO report cited above specifically adopted this interpretation. *See* Ex. A.

unreasonable, even if different in scale to other commissions the defendant paid. Specifically, the *Purcell* court held:

> Even assuming the jury was convinced that these commission were beyond the pale, the government's position that this establishes knowledge amounts to a backdoor challenge to whether MWI's interpretation was reasonable. The government's desire to avoid results like these – where the Bank may not have assessed whether a high commission represents the financing of non-U.S. employment or a bribe – might confirm that MWI's interpretation of "regular commissions" is incompatible with the Bank's basic purposes and the government's interpretation the better one. That MWI's interpretation may not be the best interpretation does not demonstrate that MWI's interpretation was necessarily unreasonable. Absent evidence that the negative consequences of an interpretation render it unreasonable, such consequences can play no role in evaluating whether an FCA defendant acted knowingly. *C.f. Safeco Ins.*, 551 U.S. at 70 n. 20. Had the government wanted to avoid such consequences, it could have defined its regulatory term to preclude them. Of course, the government may instead determine that its goals are better served by not doing so, much as the Bank officials' testimony implied. This may be the government's choice, but then the FCA may cease to be an available remedy if the government concludes after the fact that a particular commission is not "regular" because it is too high.

Id. So too here, the government's allegations correlating the size of PCCA's AWPs to historic AWPs or to the acquisition cost of its products is insufficient to plead knowledge where TRICARE "could have defined its regulatory term to preclude them." *Id.*

In fact, the Court can infer one compelling, and objectively reasonable basis by which to measure AWP from the government's allegations – PCCA's competitors. According to Complaint Exhibit 4, PCCA's AWP strategy after March 7, 2012 was to "follow [its competitor's] list of products and pricing to compete with their offering." Dkt. 66-4. In fact, as the government alleges, PCCA would have been aware of its competitors' AWPs because those AWPs were publicly reported in various third-party published compendia. Dkt. 66, ¶ 2. Moreover, few if any of the emails cited and attached to the government's Complaint reference AWP without also referencing a competitor. PCCA resisted the pressures from its customers to raise its AWPs in January 2012, after TRICARE transitioned its drug reimbursement under the D.0 Standard, Dkt. 66-1 at 1, and

sought outside guidance for how to respond to the newly unregulated market. Dkt. 66-19. In one email attached by the government, PCCA even indicated that it believed its competitors' AWP raises "look[ed] bad for the system," but unfortunately "yep it's legal." *Id.* The government's Complaint alleges no other basis for setting an AWP defined in law, or available in fact, but the AWPs set and publicly reported by PCCA and its competitors.

Even the government's own Complaint alleges facts raising serious questions about the ambiguity of what constitutes a proper or non-fraudulent AWP. As described above, the government alleges that the fraud of which it accuses PCCA began in March 2012, when PCCA is alleged to have increased some number of its products' AWP. The Court can and should draw an inference from this allegation, that the government takes no issue with PCCA's AWPs prior to March of 2012. This is paradoxical, given that while PCCA's post-March 2012 AWPs are alleged to have exceeded as much as 3,000% average acquisition costs, its pre-March 2012 AWPs are alleged to have exceeded 1,500% of average acquisition costs. *See* Dkt 66, ¶¶ 61,72. The government offers no explanation and makes no allegations in its Complaint explaining why 1,500% of average acquisition costs is reasonable, or at least non-fraudulent, while 3,000% of average acquisition cost is fraudulent. Certainly, 3,000% is larger than 1,500%, but the Complaint does not allege how either bear any rational relation to the alleged acquisition cost. At best, the government hopes that by alleging such large spreads it can sufficiently offend the Court's sensibilities as to overcome its failure to plead any AWP definition or regulatory authority explaining AWP.[13] However, its effort is, in fair review of its own allegations, absurd, and that absurdity compels dismissal of its action.

[13] Evidence of a strong profit motive or aggressive actions with the intent to earn a profit are not sufficient to show knowledge of fraud. *U.S. v. Medica-Rents Co.*, 285 F.Supp.2d 742, 774 (N.D.Tex. 2003) ("While there is evidence that Medica-Rents aggressively sought to maximize its profits by obtaining the greatest amount it could from Medicare

b. The government fails to allege any authoritative guidance cautioning against reasonable interpretations.

Next, the Court must consider whether or not the government alleges any authoritative guidance that "should have warned defendants away from their erroneous interpretation." *Safeco*, 551 U.S. at 70. Under *Safeco*, such authoritative guidance must consist of a "governmental source—either circuit court precedent or guidance from the relevant agency." *Supervalu*, 9 F.4th at 471. The government points to no such guidance in its Complaint, neither that would demonstrate that PCCA's products were covered by TRICARE, nor that its interpretation of AWP (as pleaded by the government) was not reasonable.

i. The government pleads no authoritative guidance related to TRICARE's coverage of PCCA's products.

With respect to the coverage of PCCA's products, the government states that ESI administers "prescription drug coverage for TRICARE beneficiaries . . . [for] compound prescription claims[.]" Dkt. 66, ¶ 40. The Complaint also generally describes what it takes for a pharmacy to bill TRICARE and what elements are required on a claim for a compounded medication. *Id.*, ¶¶ 41-42. It further explains, very "generally," what D.0 was and what metrics were used by TRICARE to reimburse claims for prescription medications. *Id.*, ¶ 44-45. However, the government does not affirmatively allege that non-FDA approved ingredients like those sold by PCCA are covered by TRICARE or that claims submitted for such compounded products made from these ingredients are properly payable.

The government points to no legal authority authorizing TRICARE or any federal healthcare program to reimburse, directly or indirectly, any product sold by PCCA or any

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when billing for the ROHO mattress Overlay, that is to be expected from a for-profit and its behavior does not demonstrate that Medica-Rents knew it could not bill under code E0277.")

compounded medication made from them. As discussed above, this is because, as the GAO and Department of Defense readily admit, the TRICARE regulations unequivocally prohibited the reimbursement of such non-FDA approved products.[14] As a result, the question for the Court at this stage is whether the government has pleaded any authoritative guidance that would have warned PCCA away from an otherwise objectively reasonable interpretation of existing regulations that its products were not covered and compounds made from them could not result in reimbursement by TRICARE. It assuredly has not, and the Complaint should be dismissed for failure to properly plead knowledge.

ii. The government pleads no authoritative guidance related to the definition or interpretation of AWP.

Similarly, the government does not plead any authoritative guidance that would have warned PCCA away from an interpretation that AWP could be based on the prices set and reported by market competitors. The government alleges several passages from an ESI Provider Manual (or multiple provider manuals, the allegations are not clear) that define Usual and Customary Price and warn pharmacies from submitting claims for compounded medication with inflated AWPs. Dkt. 66, ¶¶ 46-47. However, the government does not allege that PCCA had access to or knowledge of these manuals, nor any provision within the manuals that define or otherwise dictate how AWPs should be calculated by a company like PCCA. The provider manual is just that, a manual for **providers** with contractual authority to submit claims for reimbursement to TRICARE – here, pharmacies. The government does not even allege that these manuals were publicly available. More importantly, even if the government had alleged any of these things, the provider

[14] That the GAO found, and that the government in the most general way possible alleges, that TRICARE paid for compounds including non-FDA approved ingredients is of no moment, and would remain of no moment even if the government had alleged (which it does not) that PCCA knew such compounds were being reimbursed in violation of TRICARE regulations.

manuals would not meet the requirement for "authoritative guidance" laid out by *Safeco* and in any event, they do not define AWP. *See Supervalu*, 9 F.4th at 471.

Other than its undefined allegations that PCCA's AWPs were "false and fraudulent" and "fraudulently inflated" and its unexplained correlation to actual acquisition costs, the government provides no other source of definition or guidance on the term AWP.[15]

2. Even without adopting the *Safeco* standard, this District's existing precedent supports dismissing the government's Complaint for failure to adequately plead knowledge.

The current precedent in the Fifth Circuit largely aligns with the *Safeco* standard already. Courts in this Circuit have interpreted the knowledge standard of the FCA as "eliminat[ing] the prospect of liability in cases where the legality of the defendant's actions is open to debate." *U.S. ex rel. Parikh*, 977 F. Supp. 2d at 684. Indeed, though it has not opined on the applicability of *Safeco* in the FCA context, the Fifth Circuit has previously held that "[w]here there are legitimate grounds for disagreement over the scope of a contractual or regulatory provision, and the claimant's actions are in good faith, the claimant cannot be said to have knowingly presented a false claim." *U.S. v. Southland Mgmt. Corp.*, 326 F.3d 669, 684 (5th Cir. 2003) (en banc). The *Southland* standard has been recognized in this District and adopted by the Court. *See Caremark, Inc.*, 2008 WL 11280711, at *2; *U.S. ex rel. Parikh*, 977 F.Supp.2d at 684-85.

This District, in an opinion affirmed in pertinent part by the Fifth Circuit, has held unequivocally that a dispute over unclear regulatory authority cannot form the basis for FCA liability. *See U.S. ex rel. Ramadoss v. Caremark, Inc.*, 586 F. Supp. 2d 668 (W.D. Tex. 2008). This

[15] It is true that the government cites to 2003 guidance from HHS-OIG. However, this guidance does not interpret the term AWP, nor, as pleaded by the government, provide any definition of the term. Moreover, the guidance is not intended to interpret AWP, nor any TRICARE regulation, but rather to interpret the Anti-Kickback Statute. It is also guidance related to the submission of claims and the payment of kickbacks related to finished pharmaceutical products addressed expressly to "pharmaceutical manufacturer[s]," and not pharmaceutical ingredient suppliers like PCCA. The guidance further relates to Medicare and Medicaid, and not TRICARE and is sub-regulatory, meaning it would not rise to the level of "authoritative guidance" under *Safeco*.

case is very similar to *Caremark*. In that case, the government brought a FCA case, alleging in part that Caremark had created false statements or records when it notified state Medicaid, IHS, and the VA that certain restrictions applied based on certain clients' plans. *Id.* The court noted that the Medicaid regulation itself (like the TRICARE regulations related to AWP) were not clear, and that there had been no definitive guidance upon which the defendant could rely. In fact, the court stated that "this legitimate dispute based on a complex area of law is compounded by the fact that prior to [a relevant court decision], the law gave the implication that plan restrictions could be applied to Medicaid in accordance with a health plan." *Id.* at 688.

In *Caremark*, the court further found that "[t]he Government, as well as the other plaintiffs, cannot point to anything in the Medicaid statutes that objectively defines what plan restrictions can and cannot be applied." *Id.* at 689. The court rejected the government's argument "that a broad statutory interpretation concluding that Medicaid is the 'payor of last resort' is sufficient to establish clear law" that Caremark acted fraudulently as alleged by the government. *Id.* Ultimately, because the disagreement was based "on a good faith disagreement of a complex area of law" the Court found that FCA liability could not attach to Caremark's alleged conduct. *Id.*

Here, aside from generalized references to fraud and fraudulently inflated AWPs, the government does not point to any source of reliable information upon which PCCA could have relied. Like in *Caremark*, this case arises from a complex regulatory regime related to the reimbursement of compounded medications. That complexity was only magnified by the fact that the government in this case did not follow its own coverage regulations, and knowingly and intentionally exceeded its regulatory authority. The market for compounded medications made with PCCA's ingredients and the ingredients of its competitors was left wholly unregulated by the government, and the government fails to point to any statutory or regulatory text, or even circuit

court opinions that would have defined how PCCA should have conducted itself during the relevant time period. The government seems to imply that the Court should draw some inference from the difference between PCCA's AWPs and its average acquisition costs. However, the government fails to provide any basis for or meaning of that correlation. In fact, it was well-known and established by the relevant time period that no such correlation exists.

So as noted above, a fair reading of the government's allegations leads to only one conclusion. Average acquisition cost cannot be an effective or appropriate measure because there is no legal or factual support provided in the government's Complaint for correlating AWP and average acquisition costs. Publicly reported AWPs of PCCA's competitors is a more reasonable measure because, as a result of the government's conduct, the market for its products was unregulated and PCCA was without meaningful guidance applicable to its products and its business as to how to operate in that environment. This created not just a good faith dispute over the meaning of AWP, it created a wild west like market where PCCA was faced with a choice of losing all of its customers and going out of business or following the lead of the market. It goes without saying that if most businesses competing in a market have interpreted the government's regulations in the same way, the interpretation cannot fairly be called unreasonable. Since that market was left unregulated and without meaningful guidance from the government, and because the government and its agent ESI knowingly and intentionally violated their own regulations, PCCA's alleged interpretation of AWP cannot form a basis for FCA liability under *Caremark*.

F. The Court should dismiss the government's Complaint because it fails to adequately allege causation under Rule 9(b).

The government's entire case is built on a theory of causation. It acknowledges in its allegations that PCCA itself could not submit claims and did not submit claims. It alleges instead that PCCA caused the government's loss as a result of setting market AWPs. The government's

allegations related to causation do not meet the standard for particularity under Rule 9(b). There are at least three superseding causes to the government's loss in this case that make its theory of causation untenable. The first is the government's knowing violation of its own regulations in reimbursing claims for compounded medications containing bulk substances in the first instance. Second, the government intentionally chose to engage Express Scripts to reimburse claims for prescription medications under D.0 and based in part on AWP, despite being aware that Express Scripts had been accused of fraudulently profiting off of inflated AWP since as early as 2002. Third, the government has not alleged any relationship between PCCA and prescribers, and alleges only that PCCA induced and otherwise suggested submission of false claims to its pharmacy customers – who had no authority to actually prescribe the medication. On the contrary, the government's Complaint makes clear that had PCCA decided not to raise its AWPs, its customers would have simply sought their ingredients from a competitor with AWPs the Complaint alleges were inflated.

"Causation under the FCA requires proximate cause, not merely 'but for' cause." *U.S. ex rel. Morsell v. Symantec Corp.*, 471 F.Supp.3d 257, 308 (D.D.C. 2020); *see also U.S. ex rel. Cimino v. Intl. Bus. Mach. Corp.*, 3 F.4th 412, 420 (D.C. Cir. 2021). In order to prevail on an FCA claim, the Government "must demonstrate the element of causation between the false statements and the loss." *U.S. v. Miller*, 645 F.2d 473, 475-76 (5th Cir. 1981). "Under the FCA, a defendant is answerable for 'the natural, ordinary and reasonable consequences of his conduct,' though not for anything beyond that." *U.S. ex rel. Kennedy v. Aventis Pharm., Inc.*, 610 F.Supp.2d 938, 944 (N.D. Ill. 2009) (quoting *Allison Engine Co. Inc. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008)). Accordingly, FCA liability "demands more than mere passive acquiescence in the presentation of the claim and some sort of affirmative act that causes or assists the presentation of a false claim."

U.S. v. Abbott Labs., No. 3:06-CV-1769-M, 2016 WL 80000, at *7 (N.D. Tex. Jan. 7, 2016) (internal quotations omitted).

The FCA "serves a specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money[.]" *In re Baycol Prod. Litig.*, 732 F.3d 869, 874 (8th Cir. 2013). Thus, the FCA carefully defines proscribed conduct: (1) knowingly presenting or "**caus[ing] to be presented**" a false claim for payment; and (2) knowingly making, using, or "**caus[ing] to be made or used**" a false record or statement. *See* 31 U.S.C. § 3729(a)(1)-(2) (emphasis added). "The [FCA] causation standard employs traditional notions of proximate causation to determine whether there is a sufficient nexus between the conduct of the party and the ultimate presentation of the false claim . . . ." *U.S. ex rel. Wuestenhoefer v. Jefferson*, 105 F.Supp.3d 641, 681 (N.D. Miss. 2015). To establish causation, the plaintiff must show an "affirmative act" beyond "mere passive acquiescence." *U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) (*abrogated on other grounds by Cochise Consultancy, Inc. v. U.S. ex rel. Hunt*, 139 S.Ct. 1507 (2019)). Causation must be pled with particularity under Rule 9(b). *See U.S. ex rel. Osmose, Inc. v. Chem. Specialties, Inc.*, 994 F.Supp.2d 353, 366 (W.D.N.Y. Jan. 22, 2014).

The government's loss in this case is entirely attributable to its own conduct, the conduct of its agent Express Scripts, and the conduct of third party prescribers and pharmacists. In the first instance, the government's allegations make clear that the loss was inevitable regardless of which side of its Hobson's choice PCCA opted to pursue. The government's creation of a wholly unregulated market for compounded medications containing bulk substances meant PCCA had to choose between following the lead of its competitors and staying in business, or potentially going out of business. As the government alleges, that choice was wholly the creation of TRICARE and

its implementation of D.0. Dkt. 66-1 at 2. In fact, it was the effect of D.0 on compounders that started the conversation at PCCA in the first place. *Id.* Customers began emailing PCCA telling them that their competitors were raising AWPs to benefit off of the increased reimbursement under D.0. *Id.* PCCA acknowledged that the shift had already cost them several customers. *Id.* at 1. The compounding pharmacy industry's choice to put reimbursement levels over quality was leading to a market driven by the highest AWP, and not the highest quality and best priced products, as had previously been the case. *Id.*

Prior to March of 2012, PCCA believed it had "the most defensible position in the industry on quality and value with pharmacies and **with the AWP data reporting companies**." *Id.* PCCA understood that changes to reimbursement of compounded medications was likely to change the compounding industry and force it to make a choice between its focus on quality and pricing, and perhaps an unwanted focus on AWP. *Id.* As PCCA sagely predicted about the results of D.0:

> The devil's dancing and we'll see how well all of us follow as he's not likely to let up the lead. Third party payment is not operating to serve practitioners fairly and I'm not likely to be proven wrong on that notion in the long-run. Our energy will go into making the short-run go as long as it can to better financially serve the pharmacists like you who are looking after quality outcomes for their patients. Indeed, the daily fight continues!

Id. As predicted, after a few months in the newly created, unregulated market, PCCA's competitors had begun to compete not on price, but on AWP and the market for PCCA's products was now driven entirely by the AWPs set by its competitors. Dkt. 66-4. PCCA was faced with losing long time customers and significant market share to an upstart competitor competing solely on its high AWPs. *Id.* With no other guidance from the government, and no objective basis for challenging its competitor's AWPs, PCCA changed its position on AWP. *Id.* In fact, PCCA believed and communicated its belief that the inflation of AWPs was "legal, but look[ed] bad to the system." Dkt. 66-19.

This evolution of PCCA's view on AWPs and third-party reimbursement in the compounding industry generally was the direct result of TRICARE's decision to violate its own reimbursement policies with respect to its products. That transition was even more necessary after TRICARE began unlawfully reimbursing compounded medications containing bulk substances based upon AWP under D.0. Simply put, if TRICARE had followed its regulations, the government's Complaint makes clear that PCCA never would have raised its AWPs to market rates. Moreover, if TRICARE had not chosen AWP, a metric it knew to often be inflated, as a basis for reimbursement, PCCA would not have had to adopt market level AWPs. PCCA particularly did not want its customers to have to choose between the higher AWP of a competitor and the best product quality of PCCA. Thus, PCCA set market AWPs to ensure that its customers could still competitively purchase and use the highest quality product.

The government's theory of causation discounts its own unlawful activity and the role it played in its own alleged loss. They would have had PCCA choose insolvency, in spite of the fact that it believed raising its AWPs (though odious) was legal and had no guidance from any government source to the contrary. Unfortunately, however, given the unregulated market created by TRICARE, if PCCA had done what the government here considers the right thing and gone out of business, every single compound claim submitted to the government using its products would still have been submitted and satisfied with ingredients supplied by its competitors at similar market AWPs.

The government also does not once mention prescribers in its Complaint. In fact, the government does not even allege the fact that a prescription from a licensed prescriber is required before such a prescription can be dispensed. *See* 32 CFR § 199.21. As with the government's own unlawful conduct, the clinical judgment of prescribers was an intervening legal cause that preempts

any role PCCA played in the government's loss. Without an order from a prescriber, pharmacies could not bill third-party payors and would have had no need for PCCA's products in the first instance. On the other hand, had all the same orders been written by all the same prescribers at issue in this case, all of the same claims would have been submitted, regardless of where PCCA set its AWPs. This is because, as the government alleges, PCCA's competitors would have happily accepted the business of PCCA's customers and filled those orders.[16]

The government's theory of causation is nonsensical. Because PCCA responded to market conditions, and assisted its customers in understanding an otherwise undefined regulatory scheme, it "caused" them to submit claims. They allege that through the use of its PK Software and its Compound Pharmacy Management Services ("CPMS") it somehow played a role in its customers' submission of claims, including the 325 claims it lists in Exhibit 22 (including the 8 that were apparently paid in 1900: 80 years before PCCA existed). In reality, the government created a runaway train, a wild west atmosphere where anything went because TRICARE set no rules, and failed to follow the ones that it did have.

The allegations do not sufficiently plead with the requisite particularity any facts that connect, let alone make integral, the CPMS services to any submission of a claim. *Abbott Lab.*, 858 F.3d at 371 (An FCA plaintiff must plead, at a minimum, "the who, what, when, where, and how of the alleged fraud." (quoting *WMX Techs., Inc*., 112 F.3d at 179)). Any attempt to make that connection is nothing but a guesstimate that any customer followed the advice (which the Complaint does not allege) and must fail on its face. *See U.S. ex rel. Carpenter v. Abbott Lab., Inc.*, 723 F.Supp.2d 395, 406 (D. Mass. 2010) (a "guesstimate derived from anecdotal experience"

[16] Moreover, since PCCA's policy, as presented in the government's Complaint, was to set its AWPs in line with those of its competitors, under such circumstances, the government's loss – at least according to its Complaint – could have been greater.

is insufficient to state Rule 9(b) causation."). The government's allegations, even when assumed true, are clear that no part of its alleged loss would have been avoided if PCCA had fallen on its sword and refused to jump on TRICARE's runaway train. Because the government's theory of causation does not demonstrate that PCCA's conduct was the but for or proximate cause of any specific claim or set of claims submitted by third-party pharmacies to TRICARE. The government's Complaint should be dismissed.

G. The Court should dismiss the government Complaint's AKS theory because it fails to plead that PCCA sells any covered product.

The federal Anti-Kickback Statute makes it a crime to pay any type of remuneration to another individual or entity to induce or reward the referral of "any item or service for which payment **may be made** in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(2)(A) (emphasis added). PCCA has not identified any case law specifically analyzing the phrase "may be made." However, the HHS-OIG has been given authority by Congress to interpret the AKS and provide guidance on that statute, both in the form of advisory opinions and in the enforcement of its administrative and civil remedies. The OIG has consistently interpreted the statute as requiring a product that is "reimbursable." *See, e.g.*, HHS-OIG Advisory Ops. 17-05, 14-05, 11-14. HHS-OIG has construed the term "reimbursable" as meaning "covered." HHS-OIG Adv. Op. at 9 ("most third party payors do not cover the Product due to the availability of generic products; therefore, most Medicare Part D beneficiaries do not have coverage for the Product.").

Notably, the OIG typically disfavors arrangements between parties that "carve out" covered products, but include non-covered products. *Id.* at 10. However, this view is tied to the fact that providers and suppliers often sell or offer products or services that are covered and others that are not. *Id.* Thus, even if an arrangement "carves out" federally covered items or services, the

arrangement itself could be remuneration to induce or reward the purchase of covered products. *Id.* However, the OIG has indicated it would not seek enforcement in instances where the bulk of the services or items at issue are not covered (i.e. not subject to the AKS). OIG Adv. Op. 11-14. For instance, the OIG was comfortable with a co-management agreement between an ophthalmologist and an optometrist to provide post-surgical care for cataract patients receiving Premium Intraocular Lenses ("IOL"), which are not an item covered by Medicare. *Id.* at 6-8. The OIG considered the arrangement to implicate the AKS only because both parties provided other services and items that were covered, and the arrangement needed to be structured in such a way as to ensure the non-covered business was not being used as an inducement for covered business. Similarly, in Advisory Opinion 17-05, the OIG found no fault with a rewards program at a retail pharmacy, where the program only rewarded the purchases of and whose rewards could only be used on non-covered retail items.

The tension the OIG has often identified in "carve out" arrangements does not exist with respect to PCCA and its customers, because it does not sell a single product that is "covered" by any federal payor – only a registered pharmacy can sell those products. The government does not even allege that PCCA does sell a covered item or service. It simply identifies the fact that TRICARE, through Express Scripts, paid for compounded medications incorporating PCCA's products. First and foremost, this reimbursement was unlawful and in violation of the agency's own policies. As discussed more fully above, the agency had made the considered choice after notice and comment rule making not to cover compounded medications including bulk ingredients or other non-FDA approved items. The agency does not then get to simply ignore its own regulations and by doing so drag unwary parties into the purview of the AKS. It is "a well established proposition that an agency is bound by its regulations." *Kelly v. R.R. Ret. Bd.*, 625 F.2d

486, 492 (3d Cir. 1980) (citing *U.S. v. Nixon*, 418 U.S. 683, 696 (1974)). Therefore, "[a]n action undertaken by an agency contrary to its regulations is illegal and of no effect." *Id*. (citing *Vitarelli v. Seaton*, 359 U.S. 535, 545 (1959)).

Secondly, even if the Court believed "covered" should be construed more broadly to include even items expressly excluded from coverage but reimbursed nonetheless, PCCA's products still would not be covered or reimbursable. PCCA cannot bill for its products. Even in the heyday of TRICARE's unregulated market for compounded medications containing PCCA's products, it never reimbursed for or covered the actual products PCCA sold. It reimbursed the compounded medications that incorporated them. TRICARE may have based reimbursement amounts on the ingredients in the compound under D.0, but it never reimbursed the ingredients. The container of gabapentin powder mentioned above could not be dispensed by a pharmacist and then billed to TRICARE, even under D.0.

The government points to legal authority related to AWP, and tries to analogize PCCA's products to finished pharmaceutical products. However, in terms of TRICARE's coverage regulations, PCCA's products have more in common with a candy bar sold in a retail pharmacy than they do a finished pharmaceutical product dispensed in that pharmacy. In other words, one of those two items is covered by TRICARE, the other is most assuredly not. A finished pharmaceutical product if properly prescribed can, in most instances, be properly reimbursed by TRICARE once dispensed. A candy bar, even if ordered by a physician, is not allowed to be reimbursed under TRICARE's regulations, and neither is any product sold by PCCA. As such the AKS does not apply to PCCA's products and the Complaint should be dismissed.

H. The government has failed to adequately plead that PCCA's interpretation of the AKS was objectively unreasonable.

As noted above, under the Supreme Court's decision in *Safeco*, PCCA cannot be held liable under the FCA, even for an AKS violation, if it held an otherwise objectively reasonable interpretation of the law. Here, TRICARE's regulations did not allow for coverage of any product sold by PCCA, nor any compounded medication that incorporated them. It would have been objectively reasonable for PCCA to assume that its business did not fall within the purview of the AKS. This objectively reasonable interpretation of the phrase "may be made" in the AKS would subvert a finding of knowledge, and the government has failed to plead that such an interpretation would be objectively unreasonable. Thus, PCCA could not have knowingly violated the FCA, even if the government had plead the necessary elements for an AKS violation.

I. The government does not tie the alleged vacations to any specific claims.

To plausibly assert a violation of the FCA on the basis of an AKS violation, the government must plead sufficiently particular facts under Rule 9(b) to tie the alleged remuneration to specific claims for payment. In this case, the government has failed to do so with either type of remuneration it pleads. First, with respect to the so-called mega-spreads, as laid out more fully above, the government does not plead what portion any of any particular claim was improper and thus does not demonstrate that the sample claims it pleads were induced as a result of spreads created by allegedly fraudulent AWPs.

Similarly, the government alleges, generally, that PCCA paid for luxury vacations for certain, unidentified customers. *See* Dkt. 66, ¶¶ 141-149. It does not indicate how common these vacations were, or which customers actually attended them. This is fatal to their Complaint, because it fails to directly allege that the claims alleged to be false in this case were tied to that allegedly improper remuneration. It is not enough for the government to plead that some customers

received vacations and some customers submitted claims to TRICARE that included PCCA products. In fact, it is completely and equally plausible that PCCA provided vacations to some customers, but not customers submitting claims to TRICARE. The government fails to allege anything to contradict this plausible, and innocent interpretation of its allegations. Without particularized allegations to the contrary, the government's Complaint fails to state the who, what, when, where and how test of Rule 9(b) and should be dismissed.

III. The Court should dismiss the government's insufficiently pled common law claims.

A. The Court should dismiss the government's Complaint because its common law claims are wholly derivative of the FCA claims and the Complaint does not specify whether the common law claims or the FCA Claims are pled in the alternative.

As an initial matter, while the government may plead theories of payment by mistake, unjust enrichment, and fraud in a FCA complaint as long as there is no express contract between the government and the defendant, the theories may only be pleaded in the alternative and the complaint must explicitly state that the claims are pleaded in the alternative. *See, e.g.*, *U.S. ex rel. Reeves v. Mercer Transp. Co., Inc.*, 253 F.Supp.3d 1242, 1256 (M.D. Ga. 2017) ("[E]ven if the Government were allowed to proceed with these claims in the alternative, the Complaint does not indicate that its claims are asserted as alternative theories of recovery …") (citation and internal quotation marks omitted). The government fails to explicitly allege that its common law theories are pleaded in the alternative, and the claims incorporate by reference the allegations in the FCA claims. *See* Dkt. 66, ¶¶ 190-201. Accordingly, the claims must be dismissed for that reason alone.

B. The Court should dismiss the government's Complaint because it fails to adequately plead the elements of payment by mistake.

For a federal common law payment by mistake claim, "the government is entitled to reimbursement for payments . . . where it is shown: (1) payments were made (2) under the belief that they were properly owed; (3) that belief being erroneously formed; and (4) the mistaken belief

was material to the decision to pay." *U.S. v. Medica-Rents Co.*, 285 F.Supp.2d 742, 776 (N.D. Tex. 2003) (citation omitted). It is well established that a payment by mistake cannot be pleaded or proved where the plaintiff did not make payments directly to the defendant. *U.S. ex rel. Ramadoss v. Caremark Inc., et al.,* No. SA-99-CA-00914-WRF, 2008 WL 3978101 (W.D. Tex 2008). In *Caremark*, "the Court observe[d] that the case law provided by Texas suggest that the government can recover money from third parties to whom mistaken payments flowed, this situation is different from the instant case because Caremark never received the mistaken, erroneous, or wrongful payments made by Texas Medicaid." *Id.* The *Caremark* court found that plaintiffs could only "recover from the persons into whose hands the mistaken payments flowed. *Id. citing U.S. v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970) ("As the one into whose hands the mistaken payments flowed, Mead is liable to the government for each of the mistaken overpayments.").

Here, the government's allegations do not support such a finding. The government does not plead that TRICARE ever directly reimbursed PCCA, nor that PCCA ever shared in the claims paid. PCCA, according to the government's Complaint, was paid membership dues and the cost of ingredients by its member pharmacies. The pharmacies submitted the claims, but only after they had already made any necessary payments to PCCA. In other words, the proceeds did not directly flow to PCCA and the government has not alleged as much. The *Caremark* court expressly rejected the government's argument that indirect benefit in increased revenues from its non-government customers was sufficient to make out a payment by mistake claim. *Id.* Similarly here, even if the Court infers from the government's allegations that PCCA profited from increased sales of its products by inflating its AWPs, such an inference is not enough to sustain the government's cause of action for payment by mistake.[17] The government's failure to plead that the alleged mistaken

[17] *See also U.S. ex rel. Singh v. Bradford Reg. Med. Ctr.*, Civil No. 04-186 Erie, 2013 WL 4504438, at *3 (W.D. Pa.

payments were made to or flowed to PCCA is fatal to its payment by mistake claim and the government's fourth cause of action should be dismissed.[18]

C. The Court should dismiss the government's Complaint because it fails to adequately plead the elements of unjust enrichment.

To state a claim for unjust enrichment, the government must allege that a benefit was conferred upon a defendant, the defendant accepted the benefit, and it would be unjust for the defendant to retain the value of the benefit. *See, e.g.*, *Miller v. Holzmann*, Civil Action No. 95-1231(RCL), 2007 WL 710134, at *7 (D.D.C. Mar. 6, 2007). "[T]he fundamental characteristic of unjust enrichment is 'that the defendant has been unjustly enriched by receiving something . . . that properly belongs to the plaintiff[, thereby] forcing restoration to the plaintiff.'" *Rapaport v. U.S. Dept. of Treasury, Office of Thrift Supervision*, 59 F.3d 212, 217 (D.C. Cir. 1995). "Unjust enrichment is not a proper remedy simply because it is apparently easy or fair that the recipient pay some restitution for the payor's unfortunate loss or because the benefits to the recipient amount to a windfall." *U.S. v. Medica-Rents Co.*, No. 4:00-CV-483-Y, 4:01-CV-198-Y, 2006 WL 247896, at *9 (N.D. Tex. Jan. 31, 2006).

Here, the government's unjust enrichment claim fails because any benefit was conferred upon the member pharmacies in the form of allegedly excessive reimbursement of compounded medications. The government does not allege that PCCA received anything that properly belonged to the United States, and cannot, because the United States paid nothing to PCCA. The government alleges only that "PCCA was unjustly enriched at the expense of the United States" but alleges no

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Aug. 22, 2013) (rejecting the government's argument that "claims may proceed so long as the…defendants received some benefit, direct or indirect, from the United States' mistaken payments.").

[18] At least two courts have found that payment by mistake only applies in the context of a contractual arrangement. *See Medica-Rents Co.*, 2006 WL 247896, at *9 and *U.S. ex rel. Trim v. McKean*, 31 F.Supp.2d 1308, 1316 (W.D. Okla. 1998) (finding that the theories of payment by mistake and unjust enrichment may be mutually exclusive since payment by mistake requires a contractual relationship and unjust enrichment require that there be no contractual relationship). Since the government does not and cannot plead that there was a contractual relationship between TRICARE and PCCA, its payment by mistake cause of action should be dismissed for that reason as well.

facts to show that PCCA received money from the United States. This is because the only "benefit" PCCA received was from the member pharmacies through "membership fees" and purchases of ingredients. *See, e.g.*, Dkt. 66, ¶¶ 48-49. The government cannot allege that PCCA received membership dues and money for the purchase of ingredients that was actually the property of the United States. Moreover, because membership fees and costs of ingredients would have logically already been paid in advance of the submission of any claim submitted to TRICARE, there is no argument that proceeds from the government's payment of claims flowed to PCCA. Because the government does not allege that the benefit was conferred upon PCCA, and cannot plead this critical element of common law unjust enrichment, this claim must be dismissed.

The government's unjust enrichment claim should also be dismissed because its own unlawful conduct "caused" its loss. *U.S. v. Hamdan*, CRIMINAL ACTION NO. 19-60-WBV-KWR, 2020 WL 2615916, at *11 (E.D. La. May 22, 2020). In fact, in *Hamdan*, it was the government that argued unjust enrichment was not supported when the unlawful conduct by the aggrieved party caused the loss. *Id.* Under the Administrative Procedures Act, it is unlawful for an agency to act in contravention of its own regulations. *See* 5 U.S.C. § 551, *et seq*. Here, having paid out the monies at issue in knowing violation of its own regulations, TRICARE cannot now claim unjust enrichment.

D. The Court should dismiss the government's Complaint because it fails to adequately plead the elements of common law fraud.

Common law fraud typically consists of seven elements:

> (1) the defendant made a representation to the plaintiff; (2) the representation was material; (3) the representation was false; (4) when the defendant made the representation, the defendant knew it was false or made the representation recklessly and without knowledge of its truth; (5) the defendant made the representation with the intent that the plaintiff act on it; (6) the plaintiff justifiably relied on the representation; and (7) the representation caused the plaintiff injury.

Shandong Yinguang Chem. Indus. Joint Stock Co. v. Potter, 607 F.3d 1029, 1032-33 (5th Cir. 2010) (per curiam) (citing *Ernst & Young, L.L.P. v. Pac. Mut. Life Ins. Co.*, 51 S.W.3d 573, 577 (Tex. 2001)). A cause of action for common law fraud must also meet the enhanced pleading standard under Rule 9(b). *U.S. ex rel. Capshaw v. White*, Civil Action No. 3:12-CV-4457-N, 2018 WL 6523322, at *2 (N.D. Tex. Dec. 11, 2018).

The government fails to plead common law fraud for many of the reasons that it fails to state a claim under the FCA, in that its Complaint does not adequately plead falsity, causation, materiality, or, in this case, reliance. First, the common law (and common sense) understanding of fraud is that a claim cannot stand if the individual or entity claiming fraud is aware of possible inaccuracy underlying the claim, *i.e.,* a party's reliance must be justifiable. At common law, this includes when circumstances were sufficient to put someone in the allegedly defrauded party's shoes on notice that the information provided is allegedly incorrect. *See A.B.C. Packard, Inc. v. General Motors Corp.*, 275 F.2d 63, 68 n.5 (9th Cir. 1960) ("The agreements lead irresistibly to the conclusion as a matter of law that plaintiff cannot maintain that it took action in ignorance of an undisclosed policy which it would not have taken had the policy been disclosed or known to it."); *see also Fields v. Mitch Crawford's Holiday Motors Co.*, 947 S.W.2d 818, 821 (Mo. Ct. App. 1997) (reasoning that a common law fraud claim based on a material representation about a car's mileage odometer was not fraudulent because the plaintiff's "background and knowledge, sufficiently placed [the plaintiff] on notice of the odometer discrepancy" because the plaintiff "was forty years-old at the time of trial," "an experienced car buyer," "[held] a paralegal degree," "knew the odometer had been replaced," and "noticed that the odometer discrepancy box had been checked on the retail buyers order").

By contrast, the government's allegations here are insufficient because they demonstrate that ESI and TRICARE had knowledge that the AWPs were inflated and did not correspond to the acquisition price of the ingredients, and thus knew that the AWP was not meant to represent an average cost of the ingredient. *See, e.g.*, Dkt. 66, ¶ 171 ("TRICARE took this action directly in response to the exorbitant reimbursements that were being paid for compound prescription claims containing PCCA and other compound pharmaceutical suppliers' ingredients."); *supra*, Section VI. The government also fails to allege that PCCA made **any** representation whatsoever to the government. *Nat'l Rifle Assoc. of America v. Ackerman Mcqueen, Inc.*, CIVIL ACTION NO. 3:19-CV-2074-G, 2021 WL 3618113, at *16 (N.D. Tex. Aug. 16, 2021) ("That the fraudulent statement must be made to the plaintiff is baked into the elements of fraud."). The Complaint alleges only that "PCCA knowingly made material and false representations concerning the pricing of its pharmaceutical ingredients" and made those statements to third-party publishers, not to the government. *Id.*, ¶ 199. Finally, the Complaint fails to adequately allege that the government would not have made these payments if PCCA's AWPs were different, for the reasons set forth above regarding the government's continuing to pay despite its knowledge of AWP practices. Thus, the Complaint's common law fraud claim fails.

CONCLUSION

For the foregoing reasons, Defendant PCCA respectfully requests that the Court dismiss the government's Complaint-in-Partial-Intervention (Dkt. 66) under Federal Rules of Civil Procedure 12(b)(6) and 9(b).

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Respectfully submitted,

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Certificate of Service

I hereby certify that a copy of the foregoing was filed electronically with the Clerk of the Court upon all parties of record by filing in the Court's electronic filing system this 24th day of March 2022.

/s/ Anthony J. Burba